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Made by dermatologists for dermatologists.
Not too long ago when traveling I saw topical botox on a shelf in a pharmacy.

Knew at that moment I was not in the U.S. When I travel abroad, I try to stop in local pharmacies — my own version of a sociology study. I like to browse the shelves, curious to see what products are for sale. Some products I recognize, while others I’ve never seen. Checking out the sunscreens is always high on my radar; I enjoy perusing what the locals use. Most of them are recognizable global brands, but not all. My interest makes sense to me since sun protection is what we all do every day, encouraging our patients to protect their skin. While sun avoidance and protective clothing are included in these conversations, most of the time is spent talking to our patients about sunscreens. What number to use? How to prevent stinging in the eyes? What product do I recommend? And of course, what specifically do I use?

Being knowledgeable about sunscreen products is central for each of our practices. Our Acta column this month is therefore a critical read. We interview Dr. Wang about the eyes and protective clothing are included in these conversations, most of the time is spent talking to our patients about sunscreens. What number to use? How to prevent stinging in the eyes? What product do I recommend? And of course, what specifically do I use?

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Another piece I’d like to highlight is on high deductible health insurance plans. These policies are bought by rich and poor alike. Some with this insurance have no other choice — this was the only way to make insurance affordable. The burden of these deductibles falls squarely on their shoulders, making care a challenge. Other holders of these plans are on the opposite end of the spectrum, the well to do with HSA and FHA plans backing them up. Both sets of folks are now more vested in knowing the costs of things as they enter our offices since they are paying for it directly. I imagine you are seeing both of these types of patients in your practice too. Understanding how to work with this group of insured patients is a challenge we all need to be equipped for. And realizing their differences is key as well. Sort of like the sunscreens...the same and yet very different.

Enjoy your reading.

Abby S. Van Voorhees, MD, PHYSICIAN EDITOR

from the editor
ACCESS GRANTED

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Week 12 (after 2 peels)

Week 0
Week 6 (after 1 peel)
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Teledermatology - April 2015

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2017 ASHPE Gold award
Best Cover: Photo

2016 and 2015 Eddie Honorable Mention, Association/Non-profit (B-to-B) – Single article

2016 Eddie Honorable Mention, Association/Non-profit (B-to-B) – Series of articles

2015 Eddie Honorable Mention, Association/Non-profit (B-to-B) – Full issue

2014 Eddie Honorable Mention, Association/Non-profit Non-profit video

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FROM THE EDITOR

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LEGALLY SPEAKING

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Q What is your practice’s policy for no-shows or last-minute cancellations?

“We have an automated system which reminds patients by phone, email, and text of their upcoming appointment. We also say that there is a $75 no-show charge, but we do not actually follow through and bill the patients.”

– Karen Kade, MD, Miami

“There’s a shortage of dermatology appointment slots to begin with, so if there are ways to limit unfulfilled appointments, that’s better for our specialty from an access standpoint. There are studies that show if you financially incentivize people, you can influence their behavior; if people know up front that there’s a cost for not showing up, they’re more likely to come, or if allowed to cancel 24 hours in advance without penalty, more likely to cancel. Then those slots are cleared and can be used for those who need it. Hypothetically then, if every single human being worked together, it would be easy to slot someone else in who needed an appointment as soon as another person cancels.”

– Misha A. Rosenbach, MD, Philadelphia

“Send a text reminder one day before, and keep a list of patients who are waiting for an appointment in the event of a cancellation.”

– Marina Romagnoli, MD, Genoa, Italy

“We try to avoid no-shows with frequent, friendly reminders. We have three phone calls/texts/emails sent one week before, one day before, and day of appointment that mention policies in a positive manner. We try to educate patients that an empty appointment slot is time that we could have been helping a patient in need. We charge a $50 fee for cancelling within 24 hours of no-showing. If someone does no-show or late cancels, we attempt to contact them, and create a note in their chart that documents the occurrence. We only attempt to collect the fee if the patient reschedules. We are generous in writing off the charge when we hear a good excuse, but we always document the occurrence — this helps identify frequent offenders.”

– Deirdre O’Boyle Hooper, MD & Sarah C. Jackson, MD, New Orleans
What’s hot?

In this monthly column, members of the Dermatology World Editorial Advisory Workgroup identify exciting news from across the specialty.

Is your dermatopathologist imagining atypical lymphocytes in drug reactions? Probably not. Atypical lymphocytes can be part of a reactive process and not necessarily indicative of a malignant disorder. Dr. Cynthia Magro and her colleagues described a series of 20 patients with medication reactions whose biopsies showed CD30--positive atypical lymphocytes (Am J Dermatopathol. 2017;39:508-517). All patients had a rash that was temporally associated with medication exposure and resolved or improved following discontinuation of the medication. All skin biopsies showed atypical lymphocytes with positive stains for CD4 and CD30. Many of the implicated drugs were in the following categories: statins, immune modulators, angiotensin converting enzyme (ACE) inhibitors, antibiotics, and chemotherapeutic agents. Recognition of this pattern of medication reaction is important to avoid misdiagnosis as lymphomatoid papulosis or peripheral T cell lymphoma. Reactive CD 30--positive atypical lymphocytes have also been described in other inflammatory processes such as insect bite reactions, herpetic infection, scabies, perniosis, and molluscum contagiosum.

Mohs micrographic surgery patients may have more prolonged anxiety postoperatively regarding cancer diagnosis than cosmetic outcome according to a new study (Dermatol Surg. 2017;43:1029-1035). 173 patients completed a six-month follow-up study. Immediately postoperatively anxiety regarding cosmetic outcome and cancer was equal. Cosmetic anxiety diminished more quickly than cancer anxiety postoperatively. By one week, patients’ cosmetic anxiety was markedly decreased but cancer anxiety was not clinically relevantly lowered until three months postoperatively. Patients with anxiety regarding their cancer were more likely to use preoperative lorazepam. It is helpful for the Mohs surgeon to be aware of the drivers of patient anxiety in order to facilitate a better postoperative course and to improve patient satisfaction with the overall Mohs experience.

Is there a link between melanoma and Parkinson Disease (PD)? Since the early 1970s, several reports suggest that levodopa may be implicated in the development of melanoma in patients with PD. This concept seemed reasonable given that levodopa has been speculated to accelerate the growth of preexisting malignant melanomas in humans. However, a recent study using the Rochester Epidemiology Project records suggests that the two diseases may have a reciprocal relationship regardless of treatment (Mayo Clin Proc. 2017 Jul;92(7):1070-1079). The retrospective study showed that compared with controls, PD patients had a 3.8-fold increased likelihood of having a preexisting melanoma, and patients with melanoma had a 4.2-fold increased risk of developing PD. The study also revealed an increased 35-year cumulative risk of melanoma patients developing PD (11.8 percent compared to 2.6 percent in controls). Although the researchers determined that further research is warranted, perhaps dermatology providers should counsel melanoma patients on their risk of developing PD, and likewise, neurologists should refer patients for melanoma screening upon diagnosis of PD.

Rosalie Elenitsas, MD

Michel McDonald, MD

Lakshi Aldredge, MSN, ANP-BC
Is your patient immunosuppressed?

The largest multi-institutional study to date investigating the effect of immune status on disease outcome in patients with cutaneous squamous cell carcinoma of the head and neck (cSCC) who underwent surgery and received postoperative radiation therapy was recently published (Cancer. 2017 Jun 1;123(11):2054-2060.). Patients categorized as immunosuppressed had chronic hematologic malignancy, human immunodeficiency/acquired immunodeficiency syndrome, or had received immunosuppressive therapy for organ transplantation ≥ 6 months before diagnosis.

Two-thirds of the 205 patients in the study were immunocompetent and one-third was immunosuppressed. **Locoregional recurrence-free survival and progression-free survival were significantly lower in immunosuppressed patients at 2 years.**

Reinforcing our understanding of important high-risk cSCC factors, immunosuppressed status, recurrent disease, poor differentiation, and perineural invasion were significantly associated with locoregional recurrence.

Despite receiving bimodality therapy, immunosuppressed patients with cSCC had dramatically worse outcomes compared with immunocompetent patients. As immunosuppression is increasingly prevalent, this important study reminds us that immune status is a strong prognostic factor that must be identified in all patients and accounted for in our prognostic systems, treatment, and follow-up algorithms, and in clinical trial design.

Teledermatology is a rapidly increasing format for patients to access dermatologic care. With wait times long to see general dermatology, teledermatology has emerged in some areas as a vehicle to improve access to dermatology. **Store-and-forward teledermatology is the main type of telemedicine used within dermatology due in large part to the flexible timing of this format and lower costs.** The authors of a recent study demonstrate how this store-and-forward workflow can work within existing electronic health records and **significantly improve wait times to see dermatology from 70 days to 0.5 days and time to treatment from 73.5 days to 3 days (JAMA Dermatol. 2017 153(7):644-650).** This relatively new way of seeing patients can provide an effective tool to improve access to dermatologic care and may enhance clinician-to-clinician communication with better transition of care.

The interim results of the multicenter selective lymphadenectomy trial II (MSLT-II) became available in June of 2017 and showed that **there is no survival benefit for melanoma patients with a positive sentinel lymph node who undergo immediate completion lymph node dissection versus those who undergo nodal observation with ultrasonography (N Engl J Med. 376;23:2211-22).** The MSLT-II trial followed 1,939 patients over three years who were randomized into one of those two groups and followed them for recurrence and melanoma-specific death. The observation group was monitored with a clinical exam and ultrasound every 4 months for 2 years, then every 6 months for years 3 through 5. At three years there was no significant difference in the mean rate of melanoma-specific survival between the two groups (86 percent in each group). A subgroup analysis (including that based on sentinel node tumor burden) did not find any subgroup that benefited from a completion lymph node dissection. While the authors note that the dissection group had slightly less nodal recurrence at three years, they are quick to point out that when a primary endpoint lacks significance any secondary outcome must be viewed cautiously. The rates of complications in the dissection group was roughly four times that of the observation group. The results of MSLT-II, along with other trials, definitively conclude that completion lymph node dissection is not indicated for patients with a positive sentinel lymph node biopsy. **dv**
Mohs, histopathology, and repairs

BY ALEXANDER MILLER, MD

Alexander Miller, MD, addresses important coding and documentation questions each month in Cracking the Code. Dr. Miller, who is in private practice in Yorba Linda, California, represents the American Academy of Dermatology on the AMA-CPT® Advisory Committee.

During the course of Mohs surgery and subsequent reconstruction, there may be occasional instances when tissue specimens are submitted for formalin-fixed histologic processing and examination. This may be the case when “slow Mohs” is done for the interpretation of challenging histopathology, such as a lentigo maligna on severely photodamaged skin. The CPT® does not limit the Mohs surgery definition to frozen tissue processing. Rather, it specifies that a tumor must be removed and processed with the Mohs micrographic surgery technique, that histopathologic preparation is done, 100 percent of the surgical margins are examined, and that the treating physician must act in a dual role as surgeon and pathologist. Consequently, as long as the criteria for Mohs surgery are maintained, the tissue processing may be with frozen sections, formalin-fixed sections, or zinc paste.

There are instances in which legitimate Mohs surgery with frozen section tissue processing is done and additional tissue is then sent for separate formalin-fixed tissue processing and histologic evaluation. Such cases may be when a rim of tissue beyond that of the Mohs cleared margins is sent for evaluation by an outside pathologist (e.g., in cases of dermatofibrosarcoma protuberans resection). Or, one may submit a central tumor-containing tissue portion for formalin-fixed processing and histologic evaluation (e.g., melanoma in situ or invasive melanoma, for the purpose of identifying histologic prognostic criteria). Submission of tissue for formalin-fixed processing and separate histologic evaluation is expected by insurers to be an occasional, rather than routine, process linked to a Mohs surgery. The CPT Assistant, February 2014, p. 10 allows for reporting Mohs surgery codes 17311-17315 along with surgical pathology codes 88302-88309 when tissue separate from that examined for Mohs margin evaluation is submitted for formalin-fixed processing and histologic interpretation. This document, along with the AAD Position Statement on Appropriate Uses of Paraffin Sections in Association with Mohs Micrographic Surgery (www.aad.org/paraffin) may be used to appeal inappropriate Mohs surgery payment denials from insurers.
Example 1
You excise an undifferentiated pleomorphic sarcoma (malignant fibrous histiocytoma) from a Medicare patient’s scalp. As you feel that optimal histologic evaluation of excision margins would be facilitated with formalin-fixed tissue processing, you excise the tissue with the Mohs technique, cut it in blocks, color code it, and then submit it to an outside histopathology tissue-processing laboratory for slide preparation. You have trained the lab technician to embed and section the specimens following the Mohs technique. The prepared slides are sent to you for interpretation. Since you both excised and interpreted the specimens you bill CPT 17311 and 17312X2 for the three stages of Mohs surgery that were required for a tumor-free margin.

Answer: Incorrect. Although both the excision and slide interpretation were done by the treating physician, the slide preparation was done off site, and the slide preparing laboratory would commonly bill Medicare for the slide preparation with an 88305-TC CPT code. This would very likely trigger a claim denial for Mohs surgery. It is more fitting to bill for the excision with an appropriate malignant excision code and for the histopathology interpretation (professional component) with 88305-26. However, if all of the slide preparation were done on site, in the physician’s office laboratory, then the criteria for Mohs surgery would be fully satisfied.

Example 2
Excised Mohs tissue specimens of a nasal basal cell carcinoma are frozen and both hematoxylin and eosin and toluidine blue-stained slides are produced. The two stages of Mohs excision are coded with CPT 17311 and 17312.

Answer: Correct. Although two distinct tissue stains were used, each stage is coded with only one unit of Mohs surgery, and no special stain CPT code is to be used. The Mohs surgery definition includes tissue staining with both hematoxylin and eosin and toluidine blue. If a different histochemical stain were used to stain the frozen sections, it would be appropriately identified with CPT 88314.
Example 3  You reconstruct Mohs surgical defects on the same day as the Mohs surgery. Due to a fear of missing significant pathology contained in standing cones/redundant tissue excised in the course of Mohs defect reconstruction you submit this excised tissue for formalin-fixed tissue processing and evaluation by an outside pathologist, who bills for his/her service with CPT 88305. You bill the patient’s insurers for the Mohs surgeries and the claims are paid. You subsequently receive a demand for a refund of all of the previously adjudicated Mohs surgery payments. You are distraught, as you feel that you did legitimate Mohs surgery.

**Answer: Do not do this.** Based upon a correlation of Mohs codes (17311-17315) billed on the same day as histopathology code 88305 you will be identified as a rampant statistical outlier by the insurers, and you will be suspected of not having done true Mohs surgery. Furthermore, histopathologic evaluation of skin excised during post-Mohs reconstruction is not typically done. To reassure myself that I was not off base on this, I queried several respected Mohs surgeons both in academic and private practice. They all uniformly agreed that routine submission of all tissue excised in the course of reconstruction for histopathologic evaluation is not a standard practice. Risking an audit and a demand for repayment for Mohs surgeries is not worth it, as well.

Example 4  You interpret histopathology for your own patients. You submit clinically unremarkable skin excised in the course of a plastic repair of a torn earlobe for histologic evaluation. You bill the patient CPT 88304 for the slide preparation and interpretation.

**Answer: Incorrect.** The correct code is 88302, which includes “Skin, plastic repair.”

Example 5  You remove multiple pedunculated skin lesions clinically characteristic of skin tags from a patient’s neck and submit two “representative” specimens in one biopsy container. You (or the pathologist who receives the specimen) interpret the two specimens as one skin tag and one intradermal nevus. The pathology is then billed as CPT 88304 for the skin tag and 88305 for the nevus diagnoses.

**Answer: Incorrect.** The September 2000 CPT Assistant, page 10, states that when two separate tissue specimens are submitted in one container and are separately identified, then one may report one unit of histopathology service for the first specimen and another unit of service for the second specimen. Specimens submitted in one container can be separately identified by various means, such as by ink marking, by notching, or by tagging with a suture. The exact site origin of each of the individual separately marked specimens would have to be recorded and specified in the pathology report. If the specimens are not separately identified, then only one unit of histopathology interpretation is to be billed. In the above example the specimens were distinct, but their exact locations were not specified. Consequently, one may bill only one histopathology service, either CPT 88304 or 88305.
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States take on Maintenance of Certification

STATE NEWS ROUNDPUP

BY VICTORIA PASKO, MANAGER, STATE POLICY

Legislation prohibiting the use of Maintenance of Certification (MOC) as a condition of employment, reimbursement, licensure, and/or hospital privileges is proving to be one of the biggest state legislative trends this year affecting medical specialties. Nearly 30 bills related to the MOC program — which was developed by the American Board of Medical Specialties — were introduced and considered in the 2017 session, with five states enacting legislation. Currently, no state requires MOC for licensure and none have made any attempts to link the two.

**Enacted**

**Maine** enacted legislation (LD 1200) stating that the Board of Licensure in Medicine may not require physicians who are applying for initial licensure or license renewal to obtain certification from a specialty medical board or MOC as a condition of licensure.

Legislation enacted in **Georgia** (HB 165) states that physicians are not required to secure MOC as a condition of licensure to practice medicine, or as a prerequisite for employment in state medical facilities, reimbursement from third parties, or malpractice insurance coverage.

A bill enacted in **Maryland** (Maryland HB 1054/SB 989) states that the Board of Physicians may not require as a qualification to obtain a license or as a condition to renew a license: 1) certification by a national recognized accrediting organization that specializes in a specific area of medicine; or 2) MOC by a nationally recognized accrediting organization that specializes in a specific area of medicine that includes continuous reexamination to measure core competencies in the practice of medicine.

In **Tennessee**, enacted legislation (SB 298) states that the boards of medical examiners and osteopathic examination shall not deny a physician licensure based on a physician’s non-participation in any form of maintenance of licensure, including requiring any form of maintenance of licensure tied to MOC. Additionally, the board’s regular requirements, including continuing medical education, must demon-

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**Interstate Medical Licensure Compact**

The Interstate Medical Licensure Compact, now with 22 member states, requires physicians to be board certified in order to take advantage of the expedited licensing process to practice in multiple states. However, the compact does not require that participants maintain certification.

At least three specialties have come out against any legislation that prohibits linking MOC to licensure, reimbursement, and admitting privileges — including the American College of Surgeons, the American College of Obstetrics and Gynecology, and the American Society of Plastic Surgeons — citing concerns about allowing state regulators to meddle where physicians have traditionally self-regulated. Additionally, the specialties argue that such legislation weakens MOC and is a threat to patient health.

The AAD Board of Directors approved a position statement in April 2013 stating that, “Our AAD opposes the use of recertification or Maintenance of Certification (MOC) as a condition of employment, licensure or reimbursement.”

Legislation prohibiting the use of Maintenance of Certification (MOC) as a condition of employment, reimbursement, licensure, and/or hospital privileges is proving to be one of the biggest state legislative trends this year affecting medical specialties. Nearly 30 bills related to the MOC program — which was developed by the American Board of Medical Specialties — were introduced and considered in the 2017 session, with five states enacting legislation. Currently, no state requires MOC for licensure and none have made any attempts to link the two.

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strate professional competency. The bill also creates a task force that will review the overall MOC process and use of MOC by hospitals, insurance companies, and entities that license Tennessee physicians, and will make recommendations for improvement of the current process and will review alternatives for MOC.

The Texas legislation (SB 1148) prohibits MOC as a requirement for licensure, reimbursement, employment, and in some cases, hospital admitting privileges. Medical schools and national cancer institutions are excepted. The legislation was introduced by two physician legislators and was supported by the Texas Medical Association.

Pending
A bill being considered in California (SB 487) stipulates that the award of maintenance of hospital or clinical privileges, or both, shall not be contingent on participation in MOC. The bill has been referred to two committees and has had two hearings canceled.

In Michigan, legislation was introduced (HB 4134) that would prohibit any department in the state or board of medicine from requiring a physician applicant or licensee to maintain MOC.

Legislation in Ohio (HB 273) and Massachusetts (HB 2446) would prohibit MOC requirements for licensure, reimbursement, employment,
admitting privileges, or Medicaid participation. The bills have been referred to committee. The New Jersey legislation (S 3362) would prohibit requirement of MOC for all of the above except Medicaid, and has been referred to committee. A bill in Rhode Island (H 5671) states that any form of MOC may not be used as a condition of licensure and adds that current requirements, including continuous medical education, are adequate for demonstrating professional competency. The bill also contains language that would prohibit discrimination by the board of medical licensure and discipline, or any other agency or facility that accepts state funds, against physicians who do not maintain specialty medical board certification, including re-certification.

Dead Alaska (HB 191), Missouri (HB 529), Florida (HB 723), and South Carolina (H 4116) considered legislation prohibiting MOC as a requirement for

State Advocate Spotlight

Dermatology World features a grassroots advocate and their efforts to support the specialty’s advocacy agenda at the state level each month in ‘State Advocate Spotlight.’

Name: Angela Walker, MD
State: California
Issue: Advocacy
Spotlight: The American Academy of Dermatology Association (AADA) is a member of the Democratic Legislative Campaign Committee (DLCC), as well as the Republican equivalent, the RLCC. The DLCC and RLCC are comprised of state Democratic and Republican legislators in leadership positions. The AADA’s membership allows its members the opportunity to meet with state legislators, educate them on issues affecting dermatology, and raise the profile of dermatology in the advocacy sphere. Angela Walker, MD, attended the DLCC Annual Meeting in Napa, California in July.

Dermatology World: Tell me about your experiences attending political functions previous to this meeting.

Dr. Walker: I had attended the AADA Legislative Conference in 2015 and 2016. I also had some experience in residency, working to improve neighborhood bike safety.

Dermatology World: How did you prepare for this meeting?

Dr. Walker: I visited the web pages of my home state legislators and looked to see who had committee participation of interest. I was fortunate that the event identified attendees ahead of time, so I could narrow my research to those who would be present. I was also able to read about other states’ participants and recent legislation, though there were far too many attendees to know everything about each.
**Dermatology World**: What was the most important take-home message you wanted to get across to legislators?

**Dr. Walker**: I wanted legislators to identify the importance that AADA places on healthy initiatives: getting patients access to our specialty, making sure we can get them medications they need, and working on skin cancer prevention efforts.

**Dermatology World**: What were some of the biggest takeaways from your interactions with the state legislators you met?

**Dr. Walker**: It was a challenge to both seek and provide information in what were sometimes very short, spontaneous opportunities. In some ways, there were clear similarities to the standard clinic day. I needed to be direct, purposeful, and succinct in conversations. I’d usually start with a quick exchange of introductions, ask whether they had any recent or upcoming health legislation, and try to find a way to weave dermatology into the discussion, I always asked how I could help them. Some seemed genuinely thankful for the health care expertise I could provide.

It was heartening to learn that many states are pursuing important skin health bills: limiting tanning bed use for children and providing opportunities for children to apply sunscreen at school. I was caught a little off guard by one legislator’s concern that increasing use of sun protection, in particular sunscreens, might have detrimental effects on the environment. I hadn’t anticipated this response. It was a good reminder that concern for unintended consequences limits support for some initiatives. Perhaps, my next advocacy efforts will include ways to reduce packaging and enforce eco-friendly products?

**Dermatology World**: Why do you think it’s important for AADA members to participate — through the AADA or on their own — in political functions where they will have face time with state legislators?

**Dr. Walker**: I encourage physicians of all specialties to consider advocacy efforts with community leaders and legislators. We are experts whose voices can contribute to improved health in big ways. While one-on-one education with patients is critical, we’ll always be limited by what we can achieve if legislation doesn’t support our efforts. Working together with our governing leaders, we may see positive health care change. I hope advocacy is a component of my professional pursuits for years to come.

Licensure, reimbursement, employment, or admitting privileges. These bills either did not progress beyond committee referral or did not receive a vote in all referred committees before sessions ended.

In **Oregon**, HB 3081 would have prohibited requiring MOC issued by the American Board of Internal Medicine or the Osteopathic Continuous Certification as a condition of licensure, employment, admitting privileges, or reimbursement. The bill did not progress beyond committee referral.

Legislation in **Arkansas** (HB 1857) would have prohibited the Arkansas State Medical Board from requiring specialty medical board recertification or any MOC in order to be licensed to practice medicine. Hospitals and insurers may not use MOC to determine employment, admitting privileges, reimbursement, or reimbursement levels. The bill was withdrawn by the author before it reached the floor for a vote.

To read the joint statement regarding MOC from the American Academy of Dermatology (Academy) and the American Board of Dermatology (ABD), visit www.aad.org/education/moc/aad-abd-joint-statement-regarding-moc
IMPORTANT SAFETY INFORMATION

Contraindications
- Otezla® (apremilast) is contraindicated in patients with a known hypersensitivity to apremilast or to any of the excipients in the formulation.

Warnings and Precautions
- Diarrhea, Nausea and Vomiting: Cases of severe diarrhea, nausea, and vomiting have been reported with the use of Otezla. Most events occurred within the first few weeks of treatment. In some cases patients were hospitalized. Patients 65 years of age or older and patients taking medications that can lead to volume depletion or hypotension may be at a higher risk of complications from severe diarrhea, nausea, or vomiting. Monitor patients who are more susceptible to complications of diarrhea or vomiting; advise patients to contact their healthcare provider. Consider Otezla dose reduction or suspension if patients develop severe diarrhea, nausea, or vomiting.
- Depression: Treatment with Otezla is associated with an increase in depression. During clinical trials 1.3% (12/920) of patients reported depression, compared to 0.4% (2/506) on placebo. Suicidal behavior was observed in 0.1% (1/1308) of patients on Otezla, compared to 0.2% (1/506) on placebo. Carefully weigh the risks and benefits of treatment with Otezla for patients with a history of depression and/or suicidal thoughts/behavior, or in patients who develop such symptoms while on Otezla. Patients, caregivers, and families should be advised of the need to be alert for the emergence or worsening of depression, suicidal thoughts or other mood changes, and they should contact their healthcare provider if such changes occur.
- Weight Decrease: Body weight loss of 5-10% occurred in 12% (96/784) of patients treated with Otezla and in 5% (19/382) of patients treated with placebo. Monitor body weight regularly; evaluate unexplained or clinically significant weight loss, and consider discontinuation of Otezla.
- Drug Interactions: Apremilast exposure was decreased when Otezla was co-administered with rifampin, a strong CYP450 enzyme inducer; loss of Otezla efficacy may occur. Concomitant use of Otezla with CYP450 enzyme inducers (e.g., rifampin, phenobarbital, carbamazepine, phenytoin) is not recommended.
Otezla® (apremilast) is the first and only non-biologic, oral phosphodiesterase 4 (PDE4) inhibitor approved for the treatment of patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

**Oral therapy has a different look**

**PASI-75 response**
- Significant PASI-75 response vs placebo (33% vs 5%), primary endpoint, \( P < 0.0001 \)

**Mean PASI scores**
- 55% improvement in mean PASI scores vs 18% for those on placebo; data as observed

**Scalp response**
- 47% achieved an ScPGA score of clear or minimal vs 18% on placebo (\( P < 0.0001 \))

The most common (≥5%) adverse reactions were diarrhea, nausea, upper respiratory tract infection, tension headache, and headache.

The majority of patients reporting nausea and diarrhea did so within the first 2 weeks; the events tended to resolve over time with continued dosing.

Postmarketing reports of severe diarrhea, nausea, and vomiting have been associated with the use of Otezla. In some cases patients were hospitalized. Monitor patients who are more susceptible to complications of diarrhea or vomiting.

**Adverse Reactions**
- Adverse reactions reported in ≥5% of patients were (Otezla%, placebo%): diarrhea (17, 6), nausea (17, 7), upper respiratory tract infection (9, 6), tension headache (8, 4), and headache (6, 4)

**Use in Specific Populations**
- Pregnancy and Nursing Mothers: Otezla is Pregnancy Category C; it has not been studied in pregnant women. Use during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- Renal Impairment: Otezla dosage should be reduced in patients with severe renal impairment (creatinine clearance less than 30 mL/min); for details, see Dosage and Administration, Section 2, in the Full Prescribing Information.

**STUDY DESIGN**
- Otezla was evaluated in 2 multicenter, double-blind, placebo-controlled trials of similar design. Patients with moderate to severe plaque psoriasis (\( N = 1387 \)) were randomized 2:1 to Otezla 30 mg or placebo twice daily for 16 weeks, after a 5-day titration.
- Inclusion criteria: Age ≥18 years, BSA involvement ≥10%, sPGA ≥3, PASI score ≥12, candidates for phototherapy or systemic therapy.
- Results were similar between ESTEEM 1 and ESTEEM 2.
- Baseline ScPGA ≥3.

Please turn the page for Brief Summary of Full Prescribing Information.

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*Results were consistent between ESTEEM 1 and ESTEEM 2. *Week 16, secondary endpoint; all other timepoints: exploratory endpoints. ^Baseline mean PASI scores: Placebo, 19; Otezla, 19. Total, 39. ^95% confidence interval. *PASI: LOCF. *Week 16. Prospectively exploratory endpoint. In the planned hierarchical statistical testing sequence for ESTEEM 1 and ESTEEM 2, efficacy analyses preceding ScPGA were statistically significant, allowing for control of the overall type I error rate at 0.05 significance level in analysis of ScPGA. *Baseline ScPGA ≥3.
OREZLA® (apremilast) tablets, for oral use

The following is a Brief Summary; refer to Full Prescribing Information for complete product information.

INDICATIONS AND USAGE
OREZLA® (apremilast) is indicated for the treatment of patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

CONTRAINDICATIONS
OREZLA is contraindicated in patients with a known hypersensitivity to apremilast or to any of the excipients in the formulation [see Adverse Reactions (6.1)].

WARNINGS AND PRECAUTIONS
Diarrhea, Nausea, and Vomiting: There have been postmarketing reports of severe diarrhea, nausea, and vomiting associated with the use of OREZLA. Most events occurred within the first few weeks of treatment. In some cases patients were hospitalized. Patients 65 years of age or older and patients taking medications that can lead to volume depletion or hypotension may be at a higher risk of complications from severe diarrhea, nausea, or vomiting. Monitor patients who are more susceptible to complications of diarrhea or vomiting. Patients who reduced dosage or discontinued OREZLA generally improved quickly. Consider OREZLA dose reduction or suspension if patients develop severe diarrhea, nausea, or vomiting.

Depression: Treatment with OREZLA is associated with an increase in adverse reactions of depression. Before using OREZLA in patients with a history of depression and/or suicidal thoughts or behavior prescribers should carefully weigh the risks and benefits of treatment with OREZLA in such patients. Patients, their caregivers, and families should be advised of the need to be alert for the emergence or worsening of depression, suicidal thoughts or other mood changes, and if such changes occur to contact their healthcare provider. Prescribers should carefully evaluate the risks and benefits of continuing treatment with OREZLA if such events occur. During the 0 to 16 week placebo-controlled period of the 3 controlled clinical trials, 1.3% (129/920) of patients treated with OREZLA reported depression compared to 0.4% (2/506) treated with placebo. During the clinical trials, 0.1% (1/1138) of patients treated with OREZLA discontinued treatment due to depression compared with none in placebo-treated patients (0/506). Depression was reported as serious in 0.1% (1/1138) of patients exposed to OREZLA, compared to none in placebo-treated patients (0/506). Instances of suicidal behavior have been observed in 0.1% (1/1138) of patients while receiving OREZLA, compared to 0.2% (2/1138) in placebo-treated patients. In the clinical trials, one patient treated with OREZLA attempted suicide while one who received placebo committed suicide.

Weight Decrease: During the controlled period of the trials in psoriasis, weight decrease between 5%-10% of body weight occurred in 12% (96/784) of patients treated with OREZLA compared to 5% (19/382) treated with placebo. Weight decrease of ≥10% of body weight occurred in 2% (16/784) of patients treated with OREZLA 30 mg twice daily compared to 1% (3/382) patients treated with placebo. Patients treated with OREZLA should have their weight monitored regularly. If unexplained or clinically significant weight loss occurs, weight loss should be evaluated, and discontinuation of OREZLA should be considered.

Drug Interactions: Co-administration of strong cytochrome P450 enzyme inducer, rifampin, resulted in a reduction of systemic exposure of apremilast, which may result in a loss of efficacy of OREZLA. Therefore, the use of cytochrome P450 enzyme inducers (e.g., rifampin, phenobarbital, carbamazepine, phenytoin) with OREZLA is not recommended [see Drug Interactions (7.1) and Clinical Pharmacology (12.3)].

ADVERSE REACTIONS
Clinical Trials Experience in Psoriasis: Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trial of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice. Diarrhea, nausea, and upper respiratory tract infection were the most commonly reported adverse reactions. The most common adverse reactions leading to discontinuation for patients taking OREZLA were nausea (1.6%), diarrhea (1.0%), and headache (0.8%). The proportion of patients with psoriasis who discontinued treatment due to any adverse reaction was 6.1% for patients treated with OREZLA 30 mg twice daily and 4.1% for placebo-treated patients.

<table>
<thead>
<tr>
<th>Preferred Term</th>
<th>Placebo (N=506) n (%)</th>
<th>OREZLA 30 mg BID (N=920) n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diarrhea</td>
<td>32 (6)</td>
<td>160 (17)</td>
</tr>
<tr>
<td>Nausea</td>
<td>35 (7)</td>
<td>155 (17)</td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>31 (6)</td>
<td>84 (9)</td>
</tr>
<tr>
<td>Tension headache</td>
<td>21 (4)</td>
<td>75 (8)</td>
</tr>
<tr>
<td>Headache</td>
<td>19 (4)</td>
<td>55 (6)</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>11 (2)</td>
<td>39 (4)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>8 (2)</td>
<td>35 (4)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>9 (2)</td>
<td>29 (3)</td>
</tr>
<tr>
<td>Decrease appetite</td>
<td>5 (1)</td>
<td>26 (3)</td>
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<tr>
<td>Insomnia</td>
<td>4 (1)</td>
<td>21 (2)</td>
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<tr>
<td>Back pain</td>
<td>4 (1)</td>
<td>20 (2)</td>
</tr>
<tr>
<td>Migraine</td>
<td>5 (1)</td>
<td>19 (2)</td>
</tr>
<tr>
<td>Frequent bowel movements</td>
<td>1 (0)</td>
<td>17 (2)</td>
</tr>
<tr>
<td>Depression</td>
<td>2 (0)</td>
<td>12 (1)</td>
</tr>
<tr>
<td>Bronchitis</td>
<td>2 (0)</td>
<td>12 (1)</td>
</tr>
<tr>
<td>Tooth abscess</td>
<td>0 (0)</td>
<td>10 (1)</td>
</tr>
<tr>
<td>Folliculitis</td>
<td>0 (0)</td>
<td>9 (1)</td>
</tr>
<tr>
<td>Sinus headache</td>
<td>0 (0)</td>
<td>9 (1)</td>
</tr>
</tbody>
</table>

* Two subjects treated with OREZLA experienced serious adverse reaction of abdominal pain.

Severe worsening of psoriasis (rebound) occurred in 0.3% (4/1184) patients following discontinuation of treatment with OREZLA (apremilast).

DRUG INTERACTIONS
Strong CYP 450 Inducers: Apremilast exposure is decreased when OREZLA is co-administered with strong CYP450 inducers (such as rifampin) and may result in loss of efficacy [see Warnings and Precautions (5.3) and Clinical Pharmacology (12.3)].

USE IN SPECIFIC POPULATIONS
Pregnancy: Pregnancy Category C; OREZLA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Pregnancy Exposure Registry: There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to OREZLA during pregnancy. Information about the registry can be obtained by calling 1-877-311-8972.

Nursing Mothers: It is not known whether OREZLA or its metabolites are present in human milk. Because many drugs are present in human milk, caution should be exercised when OREZLA is administered to a nursing woman. Pediatric use: The safety and effectiveness of OREZLA in pediatric patients less than 18 years of age have not been established. Geriatric use: Of the 1257 patients who enrolled in two placebo-controlled psoriasis trials (PSOR 1 and PSOR 2), a total of 108 psoriasis patients were 65 years of age and older, including 9 patients who were 75 years of age and older. No overall differences were observed in the efficacy and safety in elderly patients ≥65 years of age and younger adult patients <65 years of age in the clinical trials. Renal Impairment: Apremilast pharmacokinetics were characterized in subjects with mild, moderate, and severe renal impairment as defined by a creatinine clearance of 60-89, 30-59, and less than 30 mL per minute, respectively, by the Cockcroft-Gault equation. While no dose adjustment is needed in patients with mild or moderate renal impairment, the dose of OREZLA should be reduced to 30 mg once daily in patients with severe renal impairment [see Dosage and Administration (2.2) and Clinical Pharmacology (12.3)].

Hepatic Impairment: Apremilast pharmacokinetics were characterized in patients with moderate (Child Pugh B) and severe (Child Pugh C) hepatic impairment. No dose adjustment is necessary in these patients.

OVERDOSAGE
In case of overdose, patients should seek immediate medical help. Patients should be managed by symptomatic and supportive care should there be an overdose.

Manufactured for: Celgene Corporation, Summit, NJ 07901
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Do European sunscreens outperform those in the U.S.?

BY ABBY S. VAN VOORHEES, MD

In this month’s Acta Eruditorum column, Physician Editor Abby S. Van Voorhees, MD, talks with Steven Q. Wang, MD, about his recent Journal of the American Academy of Dermatology article, “Comparison of ultraviolet A light protection standards in the United States and European Union through in vitro measurements of commercially available sunscreens.”

Q: Dr. Van Voorhees: The U.S. and the European Union have different sunscreen standards. Can you tell us what each are? Are there different standards for both UVB and UVA protection? Can you shed light on why there are these differences?

Dr. Wang: Sunscreen is regulated by the Food and Drug Administration (FDA) and treated as a drug in the U.S. In contrast, sunscreen is regulated as a cosmetic in EU. This regulatory difference helps to explain many of the issues related to sunscreens in both markets.

In terms of UVB protection, both the EU and the U.S. require human in vivo testing to measure the SPF. There is a very good harmony in terms of the testing guidelines and methodology in both regions.

When it comes to UVA protection, there is a noticeable difference. In general, the EU is much more proactive and rigorous when setting standards to regulate UVA protection in sunscreen. The EU adopted the International Organization for Standardization method 24443. The guideline specifies a minimum UVA protection factor (UVA PF) to SPF ratio of at least 1:3 for all marketed sunscreens.

For a long time, the U.S. did not have any standards or guidelines to test or label UVA protection. The change came in 2011 when the FDA issued the final ruling on the labeling and effectiveness of sunscreen. The FDA adopted the in vitro critical wavelength (CW) as a measure of assessing UVA protection. CW is defined as the wavelength at which 90 percent of the total area under the absorbance curve resides, with the absorption measured across the UV spectrum from 290 to 400nm. Specifically, the FDA ruled that only products with CW >370nm can be labeled as having “broad spectrum” protection.

It is generally believed that the U.S. standard may be more lenient compared to the EU standard for UVA protection, specifically in terms of requiring a more balanced UVA to UVB protection.

Q: Dr. Van Voorhees: Are sunscreen brands global? If I buy my same brand here in the U.S. versus in Europe is it the same or are its components different?

Dr. Wang: Globally, sunscreen is a billion-dollar industry with a number of major international brands and thousands of smaller regional brands. Because the industry is regulated globally either as cosmetics or drugs depending on the countries, sunscreen manufacturers must meet the formulation and testing standards in each country and region.

The differences in these standards pose various degrees of challenges in formulation, production, packaging and labeling of sunscreens for nearly all the international brands. Let us just use the EU and the U.S. as an example. Because the U.S. does not permit many of the new long-range UVA filters, companies need to formulate two sets of sunscreen products with different active and sometimes inactive ingredients for consumers in both regions.

In terms of active ingredients, we see many sunscreens in the EU contain Tinosorb as an active ingredient, and do not commonly contain oxybenzone. If we focus on inactive ingredients, the difference may be even greater among the different regions.

What’s Trending?

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In my mind, inactive ingredients are equally if not more important than active ingredients when formulating an effective and aesthetically elegant sunscreen. For example, most UV filters are organic compounds with a greasy and oily texture that can be aesthetically unpleasant for users. By incorporating an ideal combination and concentrations of inactive compounds, one can reduce the greasy texture and improve compliance.

So the bottom line is, if the consumer is buying a sunscreen from the same brand in different regions of the world, he or she may be getting an entirely different product.

**Q Dr. Van Voorhees: Why did you do your study? How many sunscreens did you study?**

**Dr. Wang:** As I mentioned before, balanced UV protection (i.e., having adequate UVA protection) is important, and there are different standards to measure UVA protection in both the U.S. and the EU. In the U.S., a product can claim to have adequate UVA protection or attain the broad spectrum status if it has a critical wavelength (CW) value >370nm. In the EU, the standard for attaining the broad spectrum status is that the product must meet the 1:3 ratio of UVA protection factor to SPF value, e.g. an SPF 30 sunscreen would need to have at least a UVA-PF of 10.

So our primary goal was to see how the U.S. sunscreens would measure up according to the EU standards.

We bought 20 sunscreens with SPF from 15 to 100+ at CVS in San Francisco and Winston-Salem, North Carolina. All these products passed the critical wavelength test (i.e., CW > 370nm) and attained broad-spectrum status. Keep in mind, the U.S. labeling guideline is a pass-fail test. The actual CW value of the product is not listed on the products. So we did not know the actual value of CW for these products.

We measured the actual UVA protection values for these products using two in vitro tests. The tests were conducted in accordance with the 2011 FDA final rule (U.S. standard) and the 2012 International Organization for Standardization method (EU standard).

**Q Dr. Van Voorhees: What did you find? Were most products able to pass both the U.S. and European criterion for being considered broad spectrum?**

**Dr. Wang:** A number of interesting observations came out of this study. First, 19 of the 20 sunscreens had CW > 370nm. Interestingly, one product failed our test, even though it was labeled “broad spectrum.” But only 11 of the 20 sunscreens met the EU standards, which means nearly half of the sunscreens that passed U.S. standards had failed the EU standard.

Second, we noticed an interesting trend showing that as the SPF of sunscreen increased, the number of products that do not meet the EU criteria also increased. Seven of the 8 (88 percent) sunscreens with SPF <30 passed the EU standard, 4 of 8 (50 percent) sunscreens with SPF 50 to 55+ passed, and 0 of the sunscreens with SPF 60 met the EU standard. Also, we noticed that none of the

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**More ingredients**

To learn more about the eight sunscreen ingredients approved in the EU but not in the U.S., visit www.aad.org/dw/monthly/2016/may/a-recipe-for-public-health.
sunscreens with inorganic filters (i.e., TiO2 and ZnO), regardless of the SPF values, met the EU standards.

There is a subtle but important nuance that needs to be explained. The high SPF products had higher UVA protection when compared to low SPF products. For example, the three SPF 100 products had UVA PF values ranging from 23 to 32. The low SPF (15 to 30) products had UVA PF values ranging from 6 to 14. However, the protection is not balanced; there is more UVB protection than UVA protection. That is why it did not meet the EU standard.

Third, our data also showed there is a simple way to bring the U.S. standards on par with the EU standard so that the U.S. sunscreen will have more balanced UVA to UVB protection. We don’t have to abandon CW as a test. Instead, we merely have to increase the passing value beyond the current level of 370nm. From our data, we showed that if we raised the CW from 370 to 375nm, most sunscreens with SPF <50 will meet the EU standards of 1:3 ratio. For sunscreens with much higher SPF, such as 100, our data suggest the CW may have to be raised to >385nm.

I really hope everyone appreciates this point. There is nothing wrong with the test itself (i.e., CW measurement), the problem is the pass mark set at the current level of 370nm is too low.

Dr. Wang: Spray products are very popular, especially among men and children. The ease of application is the main attractive feature for consumers. On the flip side, we know most people use significantly less sunscreen per application. Hence, the actual SPF protection is only 1/2 to 1/3 of the SPF value on the label. Consumers using spray products, in general, really do not get adequate coverage. We unfortunately did not study spray products.

We had four sunscreens with inorganic filters, with the SPF ranging from 30 to 60+. As mentioned above, none of the four products met the EU standards. We don’t know why that is the case. Obviously we had a very small sample size. Another possible explanation is related to the extinction coefficient of ZnO compared to that of avobenzone. UVA spans from 320 to 400nm. It is very difficult to extend the protection to long range UVA protection from 360nm to 400nm. The reason is that in the U.S., we only have 2 filters (i.e., avobenzone and ZnO) that protect this range. In general, a sunscreen product with good UVA protection in these ranges will have high CW value and pass the EU standards. Compared to ZnO, avobenzone has a much higher extinction coefficient and is much more effective in absorbing UVA in this range.

Dr. Van Voorhees: What were the limitations of this study?

Dr. Wang: The study had a number of limitations. First, it looked at a very small number of very popular brands of sunscreens in the U.S. These
products were selected based on their sale volume and are readily accessible to consumers. Second, we only looked at sunscreens in the lotion and cream forms. Other sunscreen categories such as spray, oil, and sticks were excluded in the study. Third, as previously mentioned, we only had four sunscreens with inorganic filters.

Despite these shortcomings, the central message of this study still holds true. We still believe that the current U.S. standard using CW >370nm is less rigorous than the EU criteria of 1:3 UVA protection factor to SPF value. Also, without access to the latest UV filters available in other parts of the world, U.S. sunscreens with relatively high SPF (ie., >50) will have a difficult time in passing the EU standards for UVA protection. For example, in our study, only four of the eight products with SPF at 50 to 50+ passed EU standards.

Q Dr. Van Voorhees: Do the findings of this study give dermatology a call to arms to get more ingredients here in the U.S.?

Dr. Wang: The simple answer is yes. The results of our study showed that it is very difficult for U.S. sunscreens with SPF >50 to meet the EU standards for UVA protection.

There are a number of reasons. First, the maximum concentration of avobenzone, a potent long range UVA filter, is limited to 3 percent in the U.S. compared to 5 percent in Europe. Second, the FDA does not allow avobenzone to be combined with inorganic filters, such as titanium dioxide and zinc oxide. Lastly, and the most important reason, is that in the U.S. the sunscreen manufacturers do not have access to a number of new and more powerful long range UVA (340 – 400 nm) filters that are available in the EU and other parts of the world.

Now, before we issue this call to arms to get more ingredients in the U.S., we should be reminded that we have been down this path a few years ago. Dermatologists, the AAD, various non-profit organizations, patient advocacy groups, and the sunscreen industry worked in concert to raise awareness on this particular issue. This effort resulted in the passage of the Sunscreen Innovation Act in 2014. Although there was a great deal of optimism initially from all parties, we have not yet seen any new UV filters approved by the FDA.

It has been three years since the passage of that legislation. I think our study may serve as a timely reminder for all parties to revisit this issue again.

This is an important issue because sunscreens can reduce the risk of skin cancer and prevent photoaging, when used appropriately and combined with other protection modalities. From clinical anecdotes and epidemiologic studies, we also know that most people prefer to use sunscreens as the sole protective modality whenever they are outdoors. So, it just makes sense that we should incorporate the latest technologies in sunscreen, a product that can save lives.

Think about this fact. The last UV filter approval in the U.S. was in 1999, 18 years ago. Would any of us be satisfied in using a computer or a phone that was made 18 years ago?
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<table>
<thead>
<tr>
<th>Stage I &amp; II patients (n=356)¹</th>
<th>RFS</th>
<th>DMFS</th>
<th>MSS</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Sensitivity</td>
<td>71%</td>
<td>70%</td>
<td>80%</td>
</tr>
<tr>
<td>RFS</td>
<td>90%</td>
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<td>DMFS</td>
<td></td>
<td>93%</td>
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</tr>
<tr>
<td>MSS</td>
<td></td>
<td></td>
<td>99%</td>
</tr>
</tbody>
</table>

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Responding to online defamation

BY CLIFFORD WARREN LOBER, MD, JD

Every month, Dermatology World covers legal issues in “Legally Speaking.” Clifford Warren Lober, MD, JD, presents legal dilemmas in dermatology every other month. He is a dermatologist in practice in Florida and a partner in the law firm Lober, Brown, and Lober.

Sarah: One of my patients just slammed me on the internet! He said I scarred his face so badly that he looks “like Frankenstein.” He called me “a butcher” and said he wouldn’t even send a dog to someone like me. I am fairly certain I know which patient made the comment and I want to sue him!

Bryan: Let’s take a deep breath and look at the situation. You’re an excellent doctor with years of experience. I know you care deeply about your patients. This makes such comments particularly hurtful, especially if they are baseless.

Sarah: You’re not kidding!

Bryan: First of all, you should forget about suing the patient. He has a First Amendment right to state his opinions, no matter how reprehensible or repugnant they are. His defense attorney would simply point out that the comments were his opinions. Only if there were factually incorrect statements, such as alleging that someone other than you did the surgery, would we have a basis for a defamation lawsuit.

If we were to pursue this matter through the courts, we would file for injunctive relief to have the comment removed and prohibit the website from re-posting it. Should we seek monetary damages, we would have to find the patient, succeed in getting a judgment against him, and then hope he was not judgment proof. Furthermore, filing suit might only bring far more attention to the matter as social media picks up on how an injured patient is now being sued by the doctor who “butchered” his face. This is known as the “Streisand effect,” named after Barbara Streisand who sued over unauthorized aerial pictures of her Pacific home only to bring incredibly more attention to the matter.

Sarah: You’re not kidding!

Bryan: The Communications Decency Act of 1996 likely precludes you from suing rating and review websites unless they substantially alter the content of the message. Section 230 of that Act states, in pertinent part, that “No provider or user of an interactive computer service shall be treated as the publisher or speaker of any information provided by another information content provider.” You are generally unable to sue a rating and review website for merely providing a venue for third parties to voice their unaltered opinions.

Sarah: I can have my friends and relatives write positive reviews so that the patient’s negative comments get buried under their glowing statements!

Bryan: “Astroturfing,” which is the creation of reviews not based on facts or actual experience, is fraud since it is specifically intended to mislead the reader into thinking the reviews were submitted by actual patients. Many of the physicians rating sites have “sniffing tools” which specifically look for astroturfing.

Sarah: O.K. But in the future I will have my patients sign an agreement either not to make negative comments about my practice or to allow me to review their comments before they are posted online. If they don’t sign the agreement I won’t accept them as patients.

Bryan: That is absolutely illegal under federal law! Congress felt that restricting consumers’ right to free speech was against public policy. The Consumer Review Fairness Act of 2016, which became law on Dec. 14, 2016, expressly prohibits you from restricting any “assessments” or “similar analysis,” “including by electronic means,” of the services you provide or requiring a consumer/patient to submit comments to you for your review or approval prior to publication.

Sarah: So that’s it? There is nothing I can do?

Suggested Topics

If you have any suggestions for topics to be discussed in this column, please email them to loberc@gmail.com.

See the February 2013 issue of Dermatology World for disclaimers.
**Bryan:** Not necessarily! The best possible outcome would be to have the website remove the comment. The first thing you should do is review the website’s rules and guidelines for accepting posts. Do the patient’s offensive comments comply with the site’s regulations? Although many physician rating sites routinely review comments to be sure they are in compliance, not all do so and even those that do conduct reviews will usually screen a comment again if they get a request to do so. When you request that the site review the offending comment, remember to be polite since those running the site did not personally create or solicit the offensive comments.

**Sarah:** What if the site does not remove the comment?

**Bryan:** Try to spin the offensive post into a marketing tool by showing your concern and compassion for patients. Realizing that you are not certain which patient made the offensive comments and realizing that HIPAA precludes your discussing individual patients without their consent, you can say, for example, “I wish I knew who this patient was. None of my patients match the situation described. If you are this patient, please contact me so that we can address this situation together.” Anyone reading this response would know that you are a caring, compassionate doctor.

When responding to an offensive comment, never argue with the patient or appear condescending to him or her. This is an extremely counterproductive way to handle the situation.

**Sarah:** I understand that I cannot create fictitious positive reviews. What about soliciting positive reviews from patients who were pleased?

**Bryan:** You can certainly ask for feedback from your patients. The overwhelming majority of your patients certainly have a favorable or exceptionally favorable opinion of you or they wouldn’t be your patients. These positive ratings will certainly dilute the rare offensive comment.

**Sarah:** That may be true, Bryan, but the offensive comment stills hurts.

**Bryan:** It actually may not be as harmful as you may imagine. Potential patients realize that even the most outstanding physicians occasionally have a dissatisfied patient. The very best restaurants and hotels in the United States, for example, have had sporadic negative comments. Would a potential patient really believe that absolutely all of any physicians’ patients actually rate him or her “5.0”? In an odd way, a rare negative comment makes otherwise exceptional ratings believable.

**Sarah:** Thanks, Bryan! 

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**Key points**

1. Unless an offensive comment is factually incorrect, it is usually unadvisable to sue a patient. No matter how offensive or repugnant, patients have a First Amendment right to express their opinions.

2. The Communications Decency Act generally prohibits you from suing a rating and review website unless it substantially altered the content of what was posted.

3. Creating reviews not based on facts or experience is fraud since it is specifically intended to mislead the reader.

4. The Consumer Review Fairness Act of 2016 prohibits you from requiring patients to submit comments to you for your review or approval prior to publication.

5. If you receive a negative review, contact the website if the comments fail to comply with the website’s rules.

6. If you cannot have the comment taken down, consider responding in a manner which reflects that you are a concerned, caring physician.

7. Never argue with a patient online and absolutely never reveal patient information that might violate HIPAA or state privacy laws.

8. Consider encouraging satisfied patients to submit comments to physician review sites. The overwhelming number of positive comments will overshadow the rare offensive comment.
MIPS: Are you ready?

DataDerm can help meet reporting requirements

By Rachna Chaudhari

If you haven’t heard of MIPS or penalties being assessed to your Medicare Part B payments, it is vital for you to understand all you need to do this year to avoid a penalty in 2019. The Medicare Access and Chip Reauthorization Act (MACRA) repealed the sustainable growth rate formula, or SGR, in 2015. This important legislation also changed Medicare payment for the future, tying payment to quality reporting. MACRA created the Merit-based Incentive Payment System (MIPS), which combines existing Medicare reporting requirements (i.e. PQRS, meaningful use (MU), and the value-based modifier) into a single entity that ties fee-for-service payment to performance on an overall physician quality score. Initially MIPS will be the pathway for most dermatologists in the Medicare program.

In order to ensure you complete the requirements for this program and don’t receive any Medicare Part B penalties in 2019, follow the steps below for maximum success.

Step 1: Check if you are exempt from the MIPS program and automatically excluded from the penalty. If you meet one of the following criteria, you do not need to participate in the program:
- See less than 100 Medicare Part B patients per year
- Have less than $30,000 in Medicare Part B allowed charges
- 2017 is your first year as a Medicare participating provider

Go to https://qpp.cms.gov/ and enter your NPI number to see if you are exempt. Remember to enter all NPI numbers affiliated with your billings to CMS. If you are exempt, you do not need to do anything and will be automatically excluded from the penalty in 2019. Remember to check back every year to ensure you are still exempt.

Step 2: If you are not exempt from reporting, visit the AADA’s Practice Management Center at www.aad.org/practicecenter/coding-and-reimbursement/macra/mips-decision-support-tool to determine which MIPS reporting option interests you. You can choose from three pathways: earning the maximum 4 percent incentive for 2019, earning a smaller incentive between 0 – 0.5 percent in 2019, or just avoiding the 4 percent penalty in 2019. The smaller the incentive, the less work you need to do. Thus, if you are only interested in doing minimal work, you should aim for just avoiding the penalty in 2019.

Step 3: Based on the pathway you select, determine if and how many quality measures, practice improvement activities, and advancing care information measures you plan to perform. For a maximum incentive, you will have to perform over a 90-day period at least:
- 6 quality measures (www.aad.org/macra/quality) on at least 50 percent of all patients (may require reporting on additional patients depending on the quality measures you select);
- 1 high-weighted practice improvement activity (or 2 medium-weighted practice improvement activities) (www.aad.org/macra/ia);
- and the base advancing care information measures (www.aad.org/macra/aci) on at least 1 patient

You would perform more if you are in a practice of 15 or more providers.

To simply avoid the penalty, you would only need to perform:
- 1 quality measure or
- 1 practice improvement activity or
- the base advancing care information measures on at least 1 patient

If you are planning to report quality measures, look through all of the quality measures applicable to dermatologists through the quality measure selection tool at www.aad.org/practicecenter/quality/quality-measures/quality-measures-selection.
It is important to note that most dermatology-specific quality measures are not reportable through claims, so if you are planning to report your performance via claims you can only select a small subset of quality measures; the selection tool indicates which measures are reportable via claims.

**Step 4:** After performing the measures and ensuring you document them appropriately, whether in your electronic health record (EHR) or paper charts, you need to report your performance to CMS. For most dermatologists, there are three options for reporting these measures to CMS:

- If you plan on reporting through your claims, please see guidance from CMS at qpp.cms.gov.
- If you plan on reporting through your EHR, contact your vendor for specific requirements.
- If you plan to report through a registry, consider DataDerm, the Academy’s registry for dermatology members to report all dermatology-applicable quality measures as well as practice improvement activities and advancing care information measures.

**Step 5:** Now it’s time to complete your reporting, following the instructions associated with your chosen method. If you are reporting your performance via DataDerm, you need to first purchase the MIPS module at https://store.aad.org/products/11349. After purchasing the module, register for an account at www.aad.org/practicecenter/quality/dataderm/enroll-now to complete profile information and sign participation and data use agreements. You will then be able to log into the dashboard online and begin entering your data for quality measures, practice improvement activities, and advancing care information. If you are entering data for the practice improvement activities category, you will only be required to attest, which is simply an acknowledgement of performing the activities required. The advancing care information category will also require an attestation similar to the previous meaningful use attestation portal through CMS whereby you will enter your numerators and denominators for each individual measure along with acknowledgement of performing the required measures. The quality category will require additional information.

If you are reporting manually, i.e., you utilize paper charts or your EHR vendor has chosen not to integrate into DataDerm, you will be expected to enter minimal patient information including patient name, medical record number, and the date of the visit for each quality measure the patient is eligible for. You will also be required to acknowledge that you performed and documented the measure accordingly. If you are currently a DataDerm participant and your EHR is integrated, you must work closely with your client account manager to ensure you are prepared for submission.

Ensure you submit data after your reporting period is complete, select your measures for submission, and sign the data consent and release agreement for confirmation of submission. DataDerm will work to prepare your data for submission to CMS. You will receive a notification from DataDerm once this data has been submitted to CMS.

**Step 6:** Double check all of your performance data and submission requirements in December 2017 to ensure you have completed everything before the performance deadline of Dec. 31, 2017. If you are reporting through DataDerm, you have until Jan. 12, 2018 to submit the data. After submission, you will then be notified by CMS in late 2018 if you will receive an incentive, penalty, or neutral adjustment for 2019.

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**Benefits of using DataDerm as your MIPS reporting mechanism**

- Is a Qualified Clinical Data Registry (QCDR), which allows the reporting of dermatology-specific quality measures that are only available in DataDerm and cannot be reported via claims or EHR submission
- Active QCDR participation can help members meet clinical performance improvement activity requirements.
- Allows attestation to advancing care information measures as well, making it a one-stop shop for reporting all three components of MIPS
Access Granted

Improving access for referrals
Access to dermatologic care remains a challenge. Provider shortages, long wait times (29 days for new patients, according to the AAD’s 2014 Dermatology Practice Profile Survey), a rising prevalence of skin cancer (with melanoma rates in the United States doubling over the past 30 years [Morb Mortal Wkly Rep. 2015;64(21):591-596]), and an aging population who present significant skin care concerns are all pressure points. How can dermatologists meet care demands while improving access for new referrals? Dermatology World explores the options, looking at the potential impact of:

- Urgent care dermatology clinics
- Group medical appointments
- Delegating care through non-physician clinicians
Urgent care dermatology clinics

No one likes going to the emergency room. But for patients who can’t get an appointment with a dermatologist, the ER is often the only option for those who can’t afford to wait. “You know there’s going to be a limited amount of time to see patients, and one of the challenges is prioritizing what really needs to be seen quickly,” says Misha Rosenbach, MD, associate professor of dermatology and internal medicine at the University of Pennsylvania. Dr. Rosenbach, the founder and current director of the university’s dermatology inpatient consult service, has championed urgent care clinics as a way to ensure that referrals who need dermatology expertise the most have a better chance at getting it as quickly as possible.

“There is an immediate benefit as far as cost of human suffering that cannot be measured or monetized...overall ease of access is improved given that there may be more room to book someone sooner into a group than a traditional clinic.”

“In my first year of service, I was usually in clinic in the morning and rounding hospital-based patients in the afternoon,” recalls Dr. Rosenbach. “We’d always start in the emergency room and see patients who had been in clinics adjacent to where my outpatient practice is in the morning who had been sent by their providers to the ER because they assumed they couldn’t get an appointment with dermatology. Later I’d be consulting on that same patient down in the ER, which was super frustrating. Super frustrating for the patient, obviously. Super frustrating for the ER, who has these patients sitting there and clogging things up, and super frustrating for us too, because it’s way easier to see a patient in your clinic with nursing staff, lighting, equipment, biopsy logs, and follow-up already in place.”

In response, Dr. Rosenbach began developing the initial concept for an urgent care dermatology clinic. In 2008, the system got its start as four reserved appointment slots two days a week, specifically available for patients with acute or blistering rashes, severe drug reactions, or changing pigmented lesions. However it quickly became clear that a more formalized process was needed as the clinic’s popularity took off. “We had designed this just for immunosuppressed patients from infectious disease, oncology, and rheumatology, but after everyone in the hospital had heard about it, they all wanted their patients to get in,” says Dr. Rosenbach. “Imagine you’re a primary care doctor with a patient in front of you, and the options are either urgent appointment within two days, or next available — which could be 40 to 90 days. If someone had a wart, they’d click urgent, if someone had acne or psoriasis they’d click urgent, and the system sort of broke.”

As a result, the clinic added a third option for patients requiring care considered non-emergency, but more severe than routine skin concerns. In order to accommodate this new classification of referrals, the university created otherwise “invisible” slots across resident and faculty schedules, in addition to utilizing Penn’s network of satellite offices. “In some ways this works really well. At our hospital access to dermatology is not even talked about as an issue, and part of that involves having rapid access to urgent slots for patients who need it,” says Dr. Rosenbach. “But it’s a big administrative project, and takes a lot of different support from schedulers, nurses and nurse practitioners who are looking at orders and triaging them, as well as different physicians who are willing to have slots in their clinic that sometimes go unfilled because they’re being held for these urgent things.”

Is the practice of reserving acute care slots an adoptable model for other practice types outside of an academic system? Yes and no, says Dr. Rosenbach. “I have friends in private practice, and the way that you build your practice’s reputation and referral base is to be accommodating when primary care doctors in the community call you with a patient. Everyone wants to keep a balance with a full practice and appropriate wait times, and so most of my friends in private practice will not have reserved slots specifically for add-ons. However, the majority of them will accommodate add-on requests when they come in, either over lunch or at the end of the day. I think it depends on each individual practice and personal style.”

Dr. Rosenbach is quick to note, however, that reserved acute care slots do not fulfill the role of an urgent care clinic. “I think most dermatologists reading this are going to end up saying, ‘yeah, when someone calls I’ll add on a patient.’ But that’s not necessarily the same thing as providing urgent care. The challenge lies with complicated or immunosuppressed patients who may be coming from an oncologist or over in rheumatology. It’s not the same as accommodating someone who asks you for a favor, but rather specifically trying to make sure we see the sickest patients most in need of acute care in the shortest amount of time.”

www.aad.org/dw
**Group medical appointments**

While the ability to be in two places at once remains limited to the realm of science fiction (and the daydreams of Elon Musk), the capability of physicians to see multiple patients at the same time is well within reach. Shared medical appointments (SMAs) have emerged as a new potential way to improve referral access through efficiency, allowing physicians to provide education, and in some cases, care, to multiple patients with similar medical conditions within the same appointment slot.

Allison Vidimos, RPh, MD, chairman of the department of dermatology at the Cleveland Clinic Lerner College of Medicine, has had particular success with the SMA model as a method for accommodating groups of pre-organ transplant patients who require dermatologic screenings prior to receiving clearance for a transplant. “We schedule eight to 12 patients at a time, and give them and their family members a brief PowerPoint presentation about the need for a pre-transplant skin exam to make sure there are no worrisome lesions, and also the need for self skin exams and skin cancer surveillance after the organ transplant,” she explains. To address patient privacy concerns, Dr. Vidimos explains that the SMA participants sign a consent form prior to the appointment about confidentiality, and following the group portion are then placed in exam rooms for full skin exams and biopsies as needed. Depending on the findings of the skin exam, personal and family history, and biopsy results, the patients are told to follow up at a specified interval after their organ transplantation surgery based on their risk factors for skin cancer.

“SMAs have definitely helped improve access for these pre-transplant patients,” she affirms.

Margaret Lee, MD, PhD, assistant professor of dermatology and pediatrics, and director of pediatric dermatology, at Boston University School of Medicine, also utilizes a group format for atopic dermatitis — a model she began piloting at Boston Children’s Hospital in 2014 and now runs at Boston Medical Center. “There are lower numbers of full-time pediatric dermatologists compared to adult dermatologists, even in major cities,” she explains. “I’m sure all of us have developed triage algorithms for getting patients in urgently when needed.” For non-urgent patients, Dr. Lee has developed the AD PEER (Atopic Dermatitis Peer Education, Empowerment & Resilience) Clinic, which includes group teaching and support as well as individual visits. “I’m committed to growing and developing it for AD, and also for other conditions down the road.” Dr. Lee says that in her experience with SMAs, the group format has allowed for patient education and support that “is impossible in the traditional clinic model,” with even long-term atopic dermatitis patients picking up new information during group discussions, “because there is only so much you can absorb along the way in any clinical setting.”

Dr. Lee acknowledges that there are some logistical hurdles involved in implementing group clinics. Whether the appointments are scheduled solely as groups or are paired with individual visits, physicians looking to hold SMAs require a conference space — a potential difficulty for dermatologists in private practice — that’s within proximity to individual clinic rooms as needed. Financial incentives may also be lacking, “due to the fact that there is no compensation model in place for physicians to provide group teaching at this time,” says Dr. Lee. “I don’t get paid directly for the time and energy that I invest into the group component. If a non-physician is going to run the group session instead, we then must train them to make sure that the medical content is accurate, which takes additional time and resources.” For Dr. Lee, though, the reimbursement issue isn’t enough to keep her from being personally involved. “I am passionate about personally participating in the group sessions while the model is being established, working in conjunction with a dermatology nurse, because I learn details about my patients and their families that sometimes don’t come out during individual visits. This ends up improving quality of care AND my job satisfaction, and I hope someday MD compensation for group visits will be possible because of this.”

While group clinics currently present some potential financial and logistical challenges to dermatologists, Dr. Lee maintains that, “I believe there is an immediate benefit as far as cost of human suffering that cannot easily be measured or monetized, and I believe that there is potential for health care cost savings over time, although this requires further study. Overall, ease of access is improved given that there may be more room to book someone sooner into a group than a traditional clinic.”

**Care delegation: looking to non-dermatologists**

So how do non-physician clinicians (NPCs) fit into the issue of dermatologic access? According to a 2016 Physician’s Practice article, “PAs in Dermatology Increase Patient Care, Revenue,” 70 percent of certified physician assistants (PAs) work in specialties outside of primary care, with 4 percent of PAs working within dermatology. While dermatologists typically aren’t hard to find in major metropolitan areas, trained NPCs can potentially fill key access gaps in areas where access to dermatologists is scarce. (For more on state-by-state non-physician clinician scope of practice laws, see Dermatology World’s May 2017 feature, “Exploring
Access Granted

alternate sources of dermatologic care,” at www.aad.org/dw/monthly/2017/may/exploring-alternate-sources-of-dermatologic-care.)

Barry Leshin, MD, a Mohs surgeon in Winston-Salem, North Carolina, says the increased utilization of non-physician providers in his large group practice has had a remarkable impact on patient access. “We established a new office in an area where dermatologic care was not previously available. We now provide service in that community through physician assistants who were trained and are overseen by our dermatologists,” he explains. “Patients with more complex problems are scheduled to see the supervising dermatologist during his weekly visit to that outlying office. Other patients are referred to one of our locations where Mohs surgery is performed. The supervising dermatologist is also available for online consultation, and regular chart review.” According to Dr. Leshin, this system of delegation has been beneficial to the smaller community by allowing more patients to be seen with expertise within the scope of dermatology. “Having a trained non-physician clinician on the front line affords access not otherwise available locally. Successful triage of more difficult problems to the dermatologist or Mohs surgeon is key to this initiative. The specialty is struggling from a manpower standpoint, and non-physician providers enable us to extend our net and enhance patient care.”

Anjana M. Patel, MPAS, PA-C, at North Atlanta Dermatology in Suwanee, Georgia, agrees — noting that when referrals aren’t able to get an appointment with dermatology, it hurts the specialty from a care and cost perspective. “At the end of the day, the patient is going to get better dermatologic care being seen in a derm practice, versus the ER,” she says. “We’ll get patients who have been to urgent care, and didn’t really have anything done for them except being told to follow-up the next day with a dermatologist. That’s totally increasing cost for the patient, not only because they have to pay for that urgent care visit, but also because when they come to see us, they end up having to pay again.”

According to Patel, NPCs can play an important role in potentially freeing up space in a physician’s schedule to deal with an incoming referral requiring immediate care or the specific expertise of a dermatologist. “Every practice runs differently as far as how they utilize PAs and midlevels. I think we may be a little bit different in that our PAs see their own established patients, in addition to a lot of the doctors’ follow-up patients,” she says. Citing a frequent example in which a dermatologist may send a patient requiring follow-up on a biopsy to a PA for a re-check, she explains, “what that allows the doctor to do is then free up an appointment for another patient who potentially needs to be seen immediately; it allows the doctor one more opening during their schedule to be able to see somebody.”

Data bears out that these shifts in care delivery are already taking place on a broader level. According to the AAD’s 2017 Burden of Skin Disease (BSD) report, only one in three people treated for skin disease in 2013 was seen by a dermatologist. (For more highlights from the BSD, see Dermatology World’s May Facts at your Fingertips at www.aad.org/dw/monthly/2017/may/shining-a-light-on-the-burden-of-skin-disease.) However, dermatologists shouldn’t perceive these changes necessarily as “giving care away,” according to Dr. Leshin, but rather as a means of efficiently getting the right patient to the right provider. “Physicians will talk about the role of midlevels in a lot of different ways, but for patients who are hampered by distance or other logistical issues in small communities that aren’t large enough to attract a derm, we still have the ability to provide them with care,” he explains. “It’s much better to have a patient see a midlevel who is trained in the specialty versus a primary care physician who isn’t adept at handling the frontline demand for dermatologic care. One of the major complaints we hear in the house of medicine is that while dermatologists are great and valuable, we’re tough to get in to see. But one way we can make that access present in certain communities is through midlevels; they enhance our efficiencies in a myriad of ways, and truly allow us to see more patients.”

Supervising non-physician clinicians

Meet Lauralee
Actual COSENTYX patient,
compensated for her time

In the 300-mg arm of the ERASURE study at Week 12:\n\begin{itemize}
\item 82% of patients achieved PASI 75 at Week 12; of those, 7 out of 10 achieved PASI 90.\n\item The majority of patients achieved clear or almost clear skin.\n\item Over 80% of patients on COSENTYX 300 mg in the ERASURE and FIXTURE studies who achieved PASI 75 at Week 12 sustained their response at Week 52.\n\end{itemize}

\*In ERASURE, % of patients achieving an end point on 150 mg vs placebo at Week 12 were: PASI 75 (71 vs 4), IGA 0 or 1 (51 vs 2), and PASI 90 (39 vs 1). In FIXTURE, results on 300 mg vs placebo at Week 12 were: PASI 75 (78 vs 6), IGA 0 or 1 (62 vs 2), and PASI 90 (54 vs 2). In FIXTURE, results on 150 mg vs placebo at Week 12 were: PASI 75 (67 vs 5), IGA 0 or 1 (63 vs 3), and PASI 90 (42 vs 2). P<0.001 for all comparisons. Similar results seen in FEATURE and JUNCTURE.\n
†In ERASURE, 59% of patients achieved PASI 90 on 300 mg vs 1% for placebo at Week 12.\n
‡In ERASURE, 65% of patients on COSENTYX 300 mg achieved IGA mod 2011 0 or 1 vs 2% of patients on placebo at Week 12.\n
§In the COSENTYX 300-mg treatment arm, 81% and 84% of patients in ERASURE and FIXTURE, respectively, who achieved PASI 75 at Week 12 sustained their response at Week 52. In the COSENTYX 150-mg treatment arm, 72% and 82% of patients in ERASURE and FIXTURE, respectively, who achieved PASI 75 at Week 12 sustained their response at Week 52.\n
See Study Design details on page 2.

INDICATIONS
COSENTYX® (secukinumab) is indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.

COSENTYX is indicated for the treatment of adult patients with active psoriatic arthritis.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
COSENTYX is contraindicated in patients with a previous serious hypersensitivity reaction to secukinumab or to any of the excipients.

Please see additional Important Safety Information on following pages.
Please see Brief Summary of full Prescribing Information on adjacent pages.
Study Designs: The ERASURE and FIXTURE studies were multicenter, randomized, double-blind, placebo-controlled trials. ERASURE evaluated adult patients who received COSENTYX 300 mg (n=245), COSENTYX 150 mg (n=245), or placebo (n=248). FIXTURE evaluated adult patients who received COSENTYX 300 mg (n=327), COSENTYX 150 mg (n=327), or a biologic active control (n=323). All patients were adults with moderate to severe plaque psoriasis who had a BSA $\geq 10\%$, PASI score $\geq 12$, and IGA mod 2011 score $\geq 3$, and were candidates for systemic therapy or phototherapy. Patients received treatment at Weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter. Patients randomized to receive placebo who were nonresponders at Week 12 were then crossed over to receive COSENTYX 300 mg or 150 mg. All patients were followed for up to 52 weeks. Coprimary end points were PASI 75 and IGA 0 or 1 (clear or almost clear) response at Week 12, evaluated using nonresponder imputation analysis (NRI).¹

ERASURE/FIXTURE Extension study is a multicenter, double-blind, randomized, uncontrolled, withdrawal study of COSENTYX in patients completing 52 weeks in the core studies. Patients treated with COSENTYX 300 mg or 150 mg during the maintenance period in either of the core studies and exhibited PASI 75 at Week 52 were eligible to be rerandomized 2:1 to continue the same COSENTYX dose or receive placebo (withdrawal from active treatment). Placebo patients who experienced relapse (defined as loss of $>50\%$ of maximum PASI improvement compared to baseline of the core study) at any visit were retreated with 5 weekly doses of COSENTYX 300 mg (n=136) or 150 mg (n=123), followed by 1 dose every 4 weeks.²

The SCULPTURE Extension study is a multicenter, uncontrolled, double-blind and open-label (from Week 156 through Week 260) extension study (n=642). Patients who completed 52 weeks of the SCULPTURE study were eligible to continue the same COSENTYX dose and regimen in the extension to Week 156. At Week 156, the study was unblinded and, based on investigator judgment, patients could switch dosing regimens (from SoR to FI regimen and from COSENTYX 150 mg to 300 mg). Results shown are for COSENTYX 300 mg FI patients who were followed for up to 208 weeks (n=188 at extension baseline, n=131 at Year 4). Primary and secondary end points were long-term safety and PASI 75/90 responses over time in PASI 75 responders at Week 12 from the core study, respectively.³⁻¹ For PsA patients without moderate to severe plaque psoriasis, starting dose is 150 mg.¹

*Double-blind from Year 1 to Year 3, open-label from Year 3 to Year 4.

†Response rates PASI 90 at Year 1 (68.5\%) and Year 4 (66.4\%).

BSA=body surface area; FI=fixed interval; IGA=Investigator’s Global Assessment; IL=interleukin; PASI=Psoriasis Area and Severity Index; PsA=psoriatic arthritis; PsO=psoriasis; SoR=start of relapse.
IMPORTANT SAFETY INFORMATION (cont)

WARNINGS AND PRECAUTIONS

Infections

COSENTYX may increase the risk of infections. In clinical trials, a higher rate of infections was observed in subjects treated with COSENTYX compared to placebo-treated subjects. In placebo-controlled clinical trials in patients with moderate to severe plaque psoriasis, higher rates of common infections such as nasopharyngitis (11.4% versus 8.6%), upper respiratory tract infection (2.5% versus 0.7%), and mucocutaneous infections with candida (1.2% versus 0.3%) were observed with COSENTYX compared with placebo. A similar increase in risk of infection was seen in placebo-controlled trials in patients with psoriatic arthritis. The incidence of some types of infections appeared to be dose-dependent in clinical studies.

Exercise caution when considering the use of COSENTYX in patients with a chronic infection or a history of recurrent infection.

Instruct patients to seek medical advice if signs or symptoms suggestive of an infection occur. If a patient develops a serious infection, the patient should be closely monitored and COSENTYX should be discontinued until the infection resolves.

Please see additional Important Safety Information on previous and following pages.

Please see Brief Summary of full Prescribing Information on adjacent pages.
IMPORTANT SAFETY INFORMATION (cont)

Pre-treatment Evaluation for Tuberculosis
Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with COSENTYX. Do not administer COSENTYX to patients with active TB infection. Initiate treatment of latent TB prior to administering COSENTYX. Consider anti-TB therapy prior to initiation of COSENTYX in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Patients receiving COSENTYX should be monitored closely for signs and symptoms of active TB during and after treatment.

Inflammatory Bowel Disease
Caution should be used when prescribing COSENTYX to patients with inflammatory bowel disease. Exacerbations, in some cases serious, occurred in patients treated with COSENTYX during clinical trials in plaque psoriasis and psoriatic arthritis. In addition, new onset inflammatory bowel disease cases occurred in clinical trials with COSENTYX. In an exploratory study in 59 patients with active Crohn’s disease, there were trends toward greater disease activity and increased adverse events in the secukinumab group as compared to the placebo group. Patients who are treated with COSENTYX should be monitored for signs and symptoms of inflammatory bowel disease.

Hypersensitivity Reactions
Anaphylaxis and cases of urticaria occurred in patients treated with COSENTYX in clinical trials. If an anaphylactic or other serious allergic reaction occurs, administration of COSENTYX should be discontinued immediately and appropriate therapy initiated.

The removable cap of the COSENTYX Sensoready® pen and the COSENTYX prefilled syringe contains natural rubber latex which may cause an allergic reaction in latex-sensitive individuals. The safe use of the COSENTYX Sensoready pen or prefilled syringe in latex-sensitive individuals has not been studied.

Vaccinations
Prior to initiating therapy with COSENTYX, consider completion of all age appropriate immunizations according to current immunization guidelines. Patients treated with COSENTYX should not receive live vaccines.

Non-live vaccinations received during a course of COSENTYX may not elicit an immune response sufficient to prevent disease.

MOST COMMON ADVERSE REACTIONS
Most common adverse reactions (≥1%) are nasopharyngitis, diarrhea, and upper respiratory tract infection.

Please see additional Important Safety Information on previous pages.
Please see Brief Summary of full Prescribing Information on adjacent pages.

This advertisement contains pictures of actual COSENTYX patients who have been compensated for their time.

COSENTYX® (secukinumab) injection, for subcutaneous use
COSENTYX® (secukinumab) injection, for subcutaneous use
Initial U.S. Approval: 2015
BRIEF SUMMARY: Please see package insert for full prescribing information.

1 INDICATIONS AND USAGE
1.1 Plaque Psoriasis
COSENTYX is indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.

1.2 Psoriatic Arthritis
COSENTYX is indicated for the treatment of adult patients with active psoriatic arthritis.

1.3 Ankylosing Spondylitis
COSENTYX is indicated for the treatment of adult patients with active ankylosing spondylitis.

4 CONTRAINDICATIONS
COSENTYX is contraindicated in patients with a previous serious hypersensitivity reaction to secukinumab or to any of the excipients [see Warnings and Precautions (5.4)].

5 WARNINGS AND PRECAUTIONS
5.1 Infections
COSENTYX may increase the risk of infections. In clinical trials, a higher rate of infections was observed in COSENTYX treated subjects compared to placebo-treated subjects. In placebo-controlled clinical trials in patients with moderate to severe plaque psoriasis, higher rates of common infections such as nasopharyngitis (11.4% versus 8.6%), upper respiratory tract infection (2.5% versus 0.7%) and mucocutaneous infections with candida (1.2% versus 0.3%) were observed with COSENTYX compared with placebo. A similar increase in risk of infection was seen in placebo-controlled trials in patients with psoriatic arthritis and ankylosing spondylitis [see Adverse Reactions (6.1)]. The incidence of some types of infections appeared to be dose-dependent in clinical studies [see Adverse Reactions (6.1)].

Exercise caution when considering the use of COSENTYX in patients with a chronic infection or a history of recurrent infection.

Instruct patients to seek medical advice if signs or symptoms suggestive of an infection occur. If a patient develops a serious infection, the patient should be closely monitored and COSENTYX should be discontinued until the infection resolves.

5.2 Pre-treatment Evaluation for Tuberculosis
Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with COSENTYX. Do not administer COSENTYX to patients with active TB infection. Initiate treatment of latent TB prior to administering COSENTYX. Consider anti-TB therapy prior to initiation of COSENTYX in patients with a positive history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Patients receiving COSENTYX should be monitored closely for signs and symptoms of active TB during and after treatment.

5.3 Inflammatory Bowel Disease
Caution should be used when prescribing COSENTYX to patients with inflammatory bowel disease. Exacerbations, in some cases serious, occurred in COSENTYX treated patients during clinical trials in plaque psoriasis, psoriatic arthritis and ankylosing spondylitis. In addition, new onset inflammatory bowel disease cases occurred in clinical trials with COSENTYX. In an exploratory study in 59 patients with active Crohn's disease, there were trends toward greater disease activity and increased adverse events in the secukinumab group as compared to the placebo group. Patients who are treated with COSENTYX should be monitored for signs and symptoms of inflammatory bowel disease [see Adverse Reactions (6.1)].

5.4 Hypersensitivity Reactions
Anaphylaxis and cases of urticaria occurred in COSENTYX treated patients in clinical trials. If an anaphylactic or other serious allergic reaction occurs, administration of COSENTYX should be discontinued immediately and appropriate therapy initiated [see Adverse Reactions (6.1)].

5.5 Risk of Hypersensitivity in Latex-sensitive Individuals
The removable cap of the COSENTYX Sensoready pen and the COSENTYX prefilled syringe contains natural rubber latex which may cause an allergic reaction in latex-sensitive individuals. The safe use of COSENTYX Sensoready pen or prefilled syringe in latex-sensitive individuals has not been studied.

5.6 Vaccinations
Prior to initiating therapy with COSENTYX, consider completion of all age appropriate immunizations according to current immunization guidelines. Patients treated with COSENTYX should not receive live vaccines.

Non-live vaccinations received during a course of COSENTYX may not elicit an immune response sufficient to prevent disease.

6 ADVERSE REACTIONS
The following adverse reactions are discussed in greater detail elsewhere in the labeling:

• Infections [see Warnings and Precautions (5.1)]
• Inflammatory Bowel Disease [see Warnings and Precautions (5.3)]
• Hypersensitivity Reactions [see Warnings and Precautions (5.4)]

6.1 Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Plaque Psoriasis
A total of 3430 plaque psoriasis subjects were treated with COSENTYX in controlled and uncontrolled clinical trials. Of these, 1641 subjects were exposed for at least 1 year.

Four placebo-controlled phase 3 trials in plaque psoriasis subjects were pooled to evaluate the safety of COSENTYX in comparison to placebo up to 12 weeks after treatment initiation, in Trials 1, 2, 3, and 4. In total, 2077 subjects were evaluated (691 to COSENTYX 300 mg group, 692 to COSENTYX 150 mg group, and 694 to placebo group) [see Clinical Studies (14) in the full prescribing information].

Table 1 summarizes the adverse reactions that occurred at a rate of at least 1% and at a higher rate in the COSENTYX groups than the placebo group during the 12-week placebo-controlled period of the placebo-controlled trials.

Table 1 Adverse Reactions Reported by Greater Than 1% of Subjects with Plaque Psoriasis Through Week 12 in Trials 1, 2, 3, and 4

<table>
<thead>
<tr>
<th>COSENTYX</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nasopharyngitis</td>
<td>79 (11.4)</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>28 (4.1)</td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>17 (2.5)</td>
</tr>
<tr>
<td>Rhinitis</td>
<td>10 (1.4)</td>
</tr>
<tr>
<td>Oral herpes</td>
<td>9 (1.3)</td>
</tr>
<tr>
<td>Pharyngitis</td>
<td>8 (1.2)</td>
</tr>
<tr>
<td>Urticaria</td>
<td>4 (0.6)</td>
</tr>
<tr>
<td>Rhinorrhea</td>
<td>8 (1.2)</td>
</tr>
</tbody>
</table>

Adverse reactions that occurred at rates less than 1% in the placebo-controlled period of Trials 1, 2, 3, and 4 through Week 12 included: sinusitis, tinea pedis, conjunctivitis, tonsillitis, oral candidiasis, impetigo, otitis media, otitis externa, inflammatory bowel disease, increased liver transaminases, and neutropenia.

Infections
In the placebo-controlled period of the clinical trials in plaque psoriasis (a total of 1382 subjects treated with COSENTYX and 694 subjects treated with placebo up to 12 weeks), infections were reported in 28.7% of subjects treated with COSENTYX compared with 18.9% of subjects treated with placebo. Serious infections occurred in 0.14% of patients treated with COSENTYX and in 0.3% of patients treated with placebo [see Warnings and Precautions (5.1)].

Over the entire treatment period (a total of 3430 plaque psoriasis subjects treated with COSENTYX for up to 52 weeks for the majority of subjects), infections were reported in 47.5% of subjects treated with COSENTYX (0.9 per patient-year of follow-up). Serious infections were reported in 1.2% of subjects treated with COSENTYX (0.015 per patient-year of follow-up).

Phase 3 data showed an increasing trend for some types of infection with increasing serum concentration of secukinumab. Candida infections, herpes viral infections, staphylococcal skin infections, and infections requiring treatment increased as serum concentration of secukinumab increased.

Neutropenia was observed in clinical trials. Most cases of secukinumab-associated neutropenia were transient and reversible. No serious infections were associated with cases of neutropenia.

Inflammatory Bowel Disease
Cases of inflammatory bowel disease, in some cases serious, were observed in clinical trials with COSENTYX. In the plaque psoriasis program, with 3430 patients exposed to COSENTYX over the entire treatment period for up to 52 weeks (2,726 patient-years), there were 3 cases (0.11 per 100 patient-years) of exacerbation of Crohn’s disease, 2 cases (0.08 per 100 patient-years) of exacerbation of ulcerative colitis, and 2 cases (0.08 per 100 patient-years) of new onset ulcerative colitis. There were no cases in placebo patients (N=793, 176 patient-years) during the 12 week placebo-controlled period.
One case of exacerbation of Crohn’s disease was reported from long-term non-controlled portions of ongoing clinical trials in plaque psoriasis [see Warnings and Precautions (5.3)].

Hypersensitivity Reactions
Anaphylaxis and cases of urticaria occurred in COSENTYX treated patients in clinical trials [see Warnings and Precautions (5.4)].

Psoriatic Arthritis
COSENTYX was studied in two placebo controlled psoriatic arthritis trials with 1003 patients (703 patients on COSENTYX and 300 patients on placebo). Of the 703 patients who received COSENTYX, 299 patients received a subcutaneous loading dose of COSENTYX (PsA1) and 404 patients received an intravenous loading dose of secukinumab (PsA2) followed by COSENTYX administered by subcutaneous injection every four weeks. During the 16-week placebo-controlled period of the trials in patients with psoriatic arthritis, the overall proportion of patients with adverse events was similar in the secukinumab and placebo-treatment groups (59% and 58%, respectively). The adverse events that occurred at a proportion of at least 2% and at a higher proportion in the COSENTYX groups than the placebo groups during the 16-week placebo-controlled period were nasopharyngitis, upper respiratory tract infection, headache, nausea, and hypercholesterolemia. The safety profile observed in patients with psoriatic arthritis treated with COSENTYX is consistent with the safety profile in psoriasis.

Similar to the clinical trials in patients with psoriasis, there was an increased proportion of patients with infections in the COSENTYX groups (29%) compared to placebo group (26%) [see Warnings and Precautions (5.1)].

There were cases of Crohn’s disease and ulcerative colitis that included patients who experienced either exacerbations or the development of new disease. There were three cases of inflammatory bowel disease, of which two patients received secukinumab and one received placebo [see Warnings and Precautions (5.3)].

Ankylosing Spondylitis
COSENTYX was studied in two placebo controlled ankylosing spondylitis trials with 590 patients (394 patients on COSENTYX and 196 patients on placebo). Of the 394 patients who received COSENTYX, 145 patients received a subcutaneous load of COSENTYX (study AS1) and 249 received an intravenous loading dose of secukinumab (study AS2) followed by COSENTYX administered by subcutaneous injection every four weeks. During the 16-week placebo-controlled period of the trials in patients with ankylosing spondylitis, the overall proportion of patients with adverse events was higher in the secukinumab groups than the placebo-treatment groups (66% and 59%, respectively). The adverse events that occurred at a proportion of at least 2% and at a higher proportion in the COSENTYX groups than the placebo groups during the 16-week placebo-controlled period were nasopharyngitis, nausea, and upper respiratory tract infection. The safety profile observed in patients with ankylosing spondylitis treated with COSENTYX is consistent with the safety profile in psoriasis.

Similar to clinical trials in patients with psoriasis, there was an increased proportion of patients with infections in the COSENTYX groups (31%) compared to the placebo group (18%) [see Warnings and Precautions (5.1)].

In the ankylosing spondylitis program, with 571 patients exposed to COSENTYX there were 8 cases of inflammatory bowel disease during the entire treatment period (5 Crohn’s (0.7 per 100 patient-years) and 3 ulcerative colitis (0.4 per 100 patient-years)). During the placebo-controlled 16-week period, there were 2 Crohn’s disease exacerbations and 1 new onset ulcerative colitis case that was a serious adverse event in patients treated with COSENTYX compared to none of the patients treated with placebo. During the remainder of the study when all patients received COSENTYX, 1 patient developed Crohn’s disease, 2 patients had Crohn’s exacerbations, 1 patient developed ulcerative colitis, and 1 patient had an ulcerative colitis exacerbation [see Warnings and Precautions (5.3)].

6.2 Immunogenicity
As with all therapeutic proteins, there is the potential for immunogenicity. The immunogenicity of COSENTYX was evaluated using an enzyme-linked immunosorbent assay-based bridging immunoassay. Less than 0.1% of subjects treated with COSENTYX developed antibodies to secukinumab in up to 52 weeks of treatment. However, this assay has limitations in detecting anti-secukinumab antibodies in the presence of secukinumab; therefore the incidence of antibody development might not have been reliably determined. Of the subjects who developed antidrug antibodies, approximately one-half had antibodies that were classified as neutralizing. Neutralizing antibodies were not associated with loss of efficacy.

The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of incidence of antibodies to COSENTYX with the incidences of antibodies to other products may be misleading.

7 DRUG INTERACTIONS
Drug interaction trials have not been conducted with COSENTYX.

7.1 Live Vaccines
Patients treated with COSENTYX may not receive live vaccinations [see Warnings and Precautions (5.6)].

7.2 Non-Live Vaccines
Patients treated with COSENTYX may receive non-live vaccinations. Healthy individuals who received a single 150 mg dose of COSENTYX 2 weeks prior to vaccination with a non-U.S. approved group C meningococcal polysaccharide conjugate vaccine and a non-U.S. approved inactivated seasonal influenza vaccine had similar antibody responses compared to individuals who did not receive COSENTYX prior to vaccination. The clinical effectiveness of meningococcal and influenza vaccines has not been assessed in patients undergoing treatment with COSENTYX [see Warnings and Precautions (5.6)].

7.3 CYP450 Substrates
A role for IL-17A in the regulation of CYP450 enzymes has not been reported. The formation of CYP450 enzymes can be altered by increased levels of certain cytokines (e.g., IL-1, IL-6, IL-10, TNFα, IFNγ) during chronic inflammation. Thus, COSENTYX, an antagonist of IL-17A, could normalize the formation of CYP450 enzymes. Upon initiation or discontinuation of COSENTYX in patients who are receiving concomitant CYP450 substrates, particularly those with a narrow therapeutic index, consider monitoring for therapeutic effect (e.g., for warfarin) or drug concentration (e.g., for cyclosporine) and consider dosage modification of the CYP450 substrate.

8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
Pregnancy Category B
There are no adequate and well controlled trials of COSENTYX in pregnant women. Developmental toxicity studies conducted with monkeys found no evidence of harm to the fetus due to secukinumab. COSENTYX should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

An embryofetal development study was performed in cynomolgus monkeys with secukinumab. No malformations or embryofetal toxicity were observed in fetuses from pregnant monkeys that were administered secukinumab weekly by the subcutaneous route during the period of organogenesis at doses up to 30 times the maximum recommended human dose (MRHD; on a mg/kg basis at a maternal dose of 150 mg/kg).

A pre- and postnatal development toxicity study was performed in mice with a murine analog of secukinumab. No treatment related effects on functional, morphological or immunological development were observed in fetuses from pregnant mice that were administered the murine analog of secukinumab on gestation days 6, 11, and 17 and on postpartum days 4, 10, and 16 at doses up to 150 mg/kg/dose.

8.3 Nursing Mothers
It is not known whether secukinumab is excreted in human milk or absorbed systemically after ingestion. Because many drugs are excreted in human milk, caution should be exercised when COSENTYX is administered to a nursing woman.

8.4 Pediatric Use
Safety and effectiveness of COSENTYX in pediatric patients have not been evaluated.

8.5 Geriatric Use
Of the 3430 plaque psoriasis subjects exposed to COSENTYX in clinical trials, a total of 230 were 65 years or older, and 32 subjects were 75 years or older. Although no differences in safety or efficacy were observed between older and younger subjects, the number of subjects aged 65 years and older was not sufficient to determine whether they responded differently from younger subjects.

10 OVERDOSAGE
Doses up to 30 mg/kg intravenously have been administered in clinical trials without dose-limiting toxicity. In the event of overdosage, it is recommended that the patient be monitored for any signs or symptoms of adverse reactions and appropriate symptomatic treatment be instituted immediately.

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A PAIN in the LEG...HIP, KNEE, ARM...

Managing contact dermatitis in patients with metal implants and prosthetics
Diaper rash, poison ivy, jewelry, latex gloves, and bleach. The cause of common contact dermatitis cases spans a number of culprits. Fortunately, for many patients once the source has been identified avoiding contact with the dermatitis perpetrator is possible. However, for patients with metal implants and prosthetics, avoiding the source of contact dermatitis may not be so easy. “For a personal care product or poison ivy, it’s easier to identify and avoid the cause of allergens,” said Christen Mowad, MD, director of the contact and occupational dermatitis clinic at Geisinger.

While metal implants and prosthetics are certainly different, the effects of these corporeal alterations are similar in that they are often challenging to manage. Dermatology World talks to experts on diagnosing, treating, and preventing contact dermatitis in patients with metal implants and prosthetics. >>
A PAIN in the LEG...HIP, KNEE, ARM...

**Metal implants: Allergic contact dermatitis**

According to the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), more than one million patients have a hip or knee replaced every year in the United States. When it comes to angioplasty, it’s estimated that each year Americans undergo roughly one million stent procedures (Circulation. 2006;113: e166-286). Additionally, according to the American Academy of Implant Dentistry, about three million Americans currently have dental implants — a figure that is expected to grow by 500,000 every year. Often, these joints, stents, and dental implants contain metal.

Unfortunately, in some cases humans and metals mix like oil and water. According to Peter Schalock, MD, member of the department of surgery (dermatology) at Geisel School of Medicine at Dartmouth, metal allergies among patients are common. “For instance, according to patch test studies, nickel allergies are present in between 17 and 20 percent of the population. So a good number of people who are getting implants are nickel allergic,” Dr. Schalock said. The most common metal culprits of allergic contact dermatitis? “Nickel would definitely be the number one,” said Dr. Schalock. “Cobalt and chromium would be in the number two and three positions.” Physicians should also keep a close eye on molybdenum, vanadium, titanium, and rhodium, advises Dr. Schalock.

Yet, patients continue to receive these implants despite the high allergy rate. “Nickel is strong, relatively cheap, and it’s effective in implants,” said Michael Sheehan, MD, from the Contact Dermatitis Center in Columbus, Indiana, and vice president of the board of directors for the American Contact Dermatitis Society. Additionally, according to Dr. Sheehan, having a metal allergy does not necessarily correlate with implant failure or hypersensitivity reactions, because although 17 to 20 percent of the population has a nickel allergy, the estimated prevalence of metal hypersensitivity reactions from orthopedic implanted devices ranges from 0 to 5 percent (Dermatitis. 2011;22: 65-79). “Patients that have a positive patch test to nickel can have a nickel-containing implant and tolerate it fine and have absolutely no issues,” Dr. Sheehan said. “We really don’t know why. The question is: what is the micro environment around the implant and what are the antigen-presenting cells in that situation? I think there’s probably a different population of antigen-presenting cells than what we have with the Langerhans cells in the epidermis.”

**Symptoms and diagnosing**

Although the correlation between metal allergy and allergic contact dermatitis is fuzzy, Dr. Schalock argues that there are several symptoms that physicians can look for when determining a reaction. “In the biggest, simplest terms you’d see device failure. You can see things like loosening of the joint where the implant doesn’t sit firmly, or adjacent, with the bone. You will see people having pain. Also, there’s something called a pseudo tumor that can form or sometimes a lymphocytic vasculitis that can form around the implants.” When it comes to the heart, “We are definitely seeing it in cardiovascular implants and stents,” Dr. Schalock said. A recent meta-analysis of nine studies on 1,223 patients compared outcomes from stent patients with a metal allergy against stent patients without an allergy, and found that patients with a metal allergy had an increased risk of in-stent restenosis (Coron Artery Dis. 2013 Dec;24(8):684-9).

How can physicians confirm that the device or implant is causing an allergic reaction? The patch test is the natural first step. “I think dermatologists feel this is the gold standard,” Dr. Schalock said. Dr. Mowad agrees and adds, “I make sure that patients and referring physicians know that the testing is not recreative of the environment of the device and it’s not predictive of future allergy. It’s really a snapshot in time and it just tells you what the patient is or is not allergic to that day. If done after the problem, it doesn’t confirm that allergy is the cause of the problem. Rather it simply says that the patient is allergic.”

Additionally, although not validated as a sole method for allergic testing, according to a recent study published in *BioMed Research International* the lymphocyte transformation test (LTT), or the Memory Lymphocyte Immunostimulation Assay (MELISA) test may be a helpful adjunctive test to the patch test (doi:10.1155/2015/910156). The in vitro LTT measures a patient’s T-cell response against a drug — or in a case
of allergic contact dermatitis, a metal. “However, the LTT is not widely available and it’s not always covered by insurance so it’s not easily obtainable,” Dr. Mowad warns.

Another possible diagnostic option is an intra-dermal test for patient allergies. “This involves injecting the metal into the skin like you would for tuberculosis,” Dr. Schalock said. “However, that does not seem to be sensitive enough. There are a lot of false positives with that test.” Similarly, the Nuss procedure — an inserted metal bar that tests for metal sensitivities — is another diagnostic test but is also not without limitations. “The consensus at the American Contact Dermatitis Society is that there are too many false positives from that test,” Dr. Schalock said.

Overall, while there are no formal diagnostic criteria for implant-induced cutaneous allergic reactions, Dr. Schalock, along with J.P. Thyssen, MD, PhD, surveyed 119 dermatologists who regularly conduct patch tests regarding their opinions on topics related to metal hypersensitivity. Using the survey results, “We tried to break them up to major and minor criteria,” Dr. Schalock said. “We didn’t validate it further than that, but we broke it up into an opinion-based major and minor criteria system for cutaneous reactions.” (View sidebar for more details on the diagnostic criteria.)

**Treatment and prevention**

If a patient with a metal implant has a clear case of allergic contact dermatitis that is affecting the efficacy of the implanted device or causing pain, the implant may need to be removed and replaced. “If the device is truly failing, then you have to replace it. If there’s a big cyst in there, the implant is loosening, or there’s severe pain, then you pretty much have no choice,” Dr. Schalock said. “You go back in and replace it with hopefully a non-allergenic device.”

However, for Dr. Schalock — and many surgeons concerned about the increasing complexity of multiple implant surgeries — sometimes the best option when treating allergic contact dermatitis from an implant is to leave well enough alone. “It’s a really big deal to go in and replace a device. If the patient is doing mostly okay, I think we try and leave them alone and manage them conservatively.” So what does managing conservatively entail? “Really the only true literature on that is doing a course of oral steroids, like prednisone. That’s about it. I think that’s going to be your choice: some sort of anti-inflammatory agent.”

Given the lack of options for treatment post-operation, the question remains: Should there be more done to prevent allergic contact dermatitis from implants? In 2016, the American Contact Dermatitis Society released a guidelines statement addressing this issue. “We don’t recommend routine patch testing for

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**METAL IMPLANTS: Diagnostic criteria**

While there are no formal diagnostic criteria for implant-induced cutaneous allergic reactions, Peter Schalock, MD, from the department of surgery (dermatology) at Dartmouth University, along with J.P. Thyssen, MD, PhD, surveyed 119 dermatologists who regularly conduct patch tests regarding their opinions on topics related to metal hypersensitivity ([Dermatitis. 2013 Jul-Aug;24(4):183-5](https://doi.org/10.1111/der.2013.24.issue-4)). Using the survey results, “We tried to break them up to major and minor criteria,” Dr. Schalock said. “We didn’t validate it further than that, but we broke it up into an opinion-based major and minor criteria system for cutaneous reactions.” Overall, 80 and 61 percent of respondents found the following major and minor criteria helpful respectively:

**Four major criteria:**

1. Chronic dermatitis beginning weeks to months after metallic implantation
2. Eruption overlying the metal implant
3. Positive patch test to a metal component of the implant
4. Complete clearing after removal of the potentially allergenic implant

**Five minor criteria:**

1. Systemic allergic dermatitis reaction
2. Therapy-resistant dermatitis
3. Morphology consistent with dermatitis
4. Histology consistent with allergic contact dermatitis
5. Positive in vitro tests to metals (LTT)
all patients who have implants, but there are a couple of key situations where you do want to do pre-implant patch testing,” Dr. Sheehan said. “Any patient who has a history of metal sensitivity or allergic contact dermatitis to metals really would benefit from patch testing prior to having an implant placed. The other situation is if a patient has had a previous implant that failed for unknown reasons — those patients may also benefit from pre-implant patch testing.”

“Patch testing for evaluation of hypersensitivity to implanted metal devices: A perspective from the American Contact Dermatitis Society”

To view the ACDS’s guidelines on metal hypersensitivity reaction testing, visit http://journals.lww.com/dermatitis/Fulltext/2016/11000/Patch_Testing_for_Evaluation_of_Hypersensitivity.15.aspx.

Of course, there are a few caveats when it comes to choosing allergy avoidance over a metal implant. “One is the emergent situation: You’re having a heart attack and you need to get a stent and many of the stents contain nickel. In that case, it doesn’t matter. Life-saving therapy trumps contact dermatitis,” Dr. Schalock said. Additionally, allergic contact dermatitis may be unavoidable if a patient needs a complex orthopedic device replaced but there are no non-allergenic options available. “I’ve run into these situations where your choices are essentially using the allergenic device or amputation or fusion of the knee. In those situations, you have to approach it with truly informed consent where the patient is very aware of the situation: ‘A small amount of metal is being used, but we don’t have a better choice, so let’s take the chance.’”

All told, allergic contact dermatitis from metal implants is a tricky condition to identify and diagnose. “There are clear instances where there’s a correlation between metal plate allergy with overlying dermatitis,” Dr. Mowad said. “The more difficult part is when, for example, the complaint is joint pain or joint loosening. Did the allergy cause the loosening or did the loosening cause the sensitization?” However, for Dr. Mowad, beyond diagnostic testing, there’s a role for dermatology in terms of managing provider and patient expectations. “Patients come for testing and we aren’t necessarily giving them a definitive answer. I don’t think they always understand that, so I think there needs to be education about what information can be had from the patch testing. It’s very challenging and important to manage and set expectations.”

A HISTORY of PROSTHETICS

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>424 B.C.</td>
<td>Wooden foot documented in Herodotus writings</td>
</tr>
<tr>
<td>300 B.C.</td>
<td>Bronze and iron below-knee leg with wooden core (discovered 1858 in Capua, Italy)</td>
</tr>
<tr>
<td>23-79 A.D.</td>
<td>Iron hand fastened to shield for Second Punic War (218-210 B.C.) documented by Pliny the Elder</td>
</tr>
<tr>
<td>476-1000</td>
<td>Hand hook and peg legs utilized to mask deformities or battle injuries</td>
</tr>
<tr>
<td>1400s</td>
<td>Advancement in prosthetics to iron, steel, copper, and wood models</td>
</tr>
<tr>
<td>1508</td>
<td>Natural hand movement introduced with Gotz von Berlichingen’s advanced iron hand made with series of springs and releases</td>
</tr>
<tr>
<td>1529</td>
<td>“Father of amputation surgery and prosthetic design” Ambroise Pare modernized amputation surgery procedures using ligatures or bindings to improve survival rates</td>
</tr>
<tr>
<td>1536</td>
<td>Pare developed upper- and lower-extremity prostheses; invented above-knee peg leg and foot prosthesis using adjustable harness and knee-lock control</td>
</tr>
</tbody>
</table>
Prosthetics: Irritant contact dermatitis

Although sometimes lumped together, contact dermatitis caused by prosthetics is quite different from that caused by metal implants. “I think the prosthesis issue is quite distinct and different from the implant issue,” said Col. Jon Meyerle, MD, associate professor in the department of dermatology at Uniformed Services University of the Health Sciences. While implant patients may suffer from allergic contact dermatitis, patients with prostheses may be more likely to experience irritant contact dermatitis, as well as a host of other health-related issues. “It’s an environment that lends itself to a lot of irritants: the heat and friction,” Dr. Sheehan said. “The residual limb is not designed to be weight bearing, so when you put that into the underlying sock and socket, the heat and moisture and lack of air movement all create an environment that is susceptible to irritant contact dermatitis.”

According to the Amputee Coalition, roughly 2 million Americans are currently living with limb loss — 54 percent from vascular disease, 45 percent from trauma, and less than 2 percent from cancer (Arch Phys Med Rehabil. 2008; 89(3):422-9).

Symptoms and diagnosing

For this population, it’s estimated that the prevalence of stump-site irritant dermatoses ranges from 34 to 74 percent. “Itching, burning, and stinging are all very common. As the reaction persists, with time it becomes more hyper-pigmented and lichenified,” Dr. Sheehan explained. “Then some of the things we’re more concerned about is if the skin starts to break down and become ulcerated which can lead to infections.” A cross-sectional health questionnaire of Vietnam War veterans with combat-related amputation found that roughly 25 percent experienced skin breakdown, 22 percent experienced rash, 21 percent experienced abrasion, and nearly 62 percent experienced pain (Arch Dermatol. 2012; 148(11):1283-6).

Moreover, the symptoms of prosthetic irritant dermatitis often span beyond irritation and infection. “When you have contact dermatitis you can become sensitized to other things that you might not have been sensitized to otherwise,” Dr. Meyerle said. Additionally, “that discomfort leads to what we call prosthesis abandonment, meaning the person stops wearing their prosthesis because it hurts and it’s uncomfortable.” Indeed, almost 56 percent of the Vietnam War veterans did not use or limited their use of the prosthesis as a result of the dermatoses.

Read more about the history of prosthetics at www.amputee-coalition.org/resources/a-brief-history-of-prosthetics.
When their prosthesis bothers them, they stop wearing it. That has its own set of issues: quality of life, they can’t work, and the list goes on and on. That has its own morbidity associated with it that leads to other issues — social issues and depression.

When it comes to diagnosing the problem, the provider will likely want to confirm that the contact dermatitis is not attributed to metal exposure. “You want to confirm it with a North American patch test which will capture most of the allergens that would commonly be an issue,” Dr. Meyerle said. However, prostheses in the U.S. are mostly made of plastic. “There’s not a lot direct contact between metal and the skin,” Dr. Meyerle said. “You can leak some metals when it gets really moist in there, but for the most part your socket is just sitting in a plastic cup.” Therefore, the underlying cause behind stump dermatitis is often frictional and mechanical — irritant contact dermatitis, as opposed to allergic contact dermatitis.

Treatment and prevention
For prosthetic patients with irritant contact dermatitis, Dr. Meyerle recommends using emollients and then topical corticosteroids. “If they have verrucous hyperplasia from a poorly fitting prosthesis, you have to work with a prostheticist on making it fit better.” Of course, Dr. Sheehan contends that the best treatment is to prevent the issue in the first place. “One of my goals is to make sure that we work closely with the prosthetic clinic and that the prosthesis is fitting well. If the prosthesis is not fitting well, then that’s going to cause a significant problem.”

It’s also important to keep in mind that a prosthesis that is initially comfortable may cause irritation down the road. “The prosthesis may have to be redone as a patient’s leg or arm remodels over time — they lose or gain muscle, they might get bone spurs, they get old and may lose subcutaneous tissue — so that’s a continuous process,” Dr. Meyerle said. “Obviously, those who have good access to care and can get out of their house and are mobile get their prostheses modified regularly enough that they can prevent some of the friction issues that develop.”

Additionally, Dr. Sheehan contends that educating patients about proper skin care can minimize complications

AMPUTATIONS: By the numbers

According to the Amputee Coalition:

**Roughly 2 million Americans are currently living with limb loss** — 54 percent from vascular disease, 45 percent from trauma, and less than 2 percent from cancer (Arch Phys Med Rehabil. 2008; 89(3):422-9)

**Each year, about 185,000 amputations** occur (HHS, CDC, NCHS; 1998)

**Hospital costs associated with amputation were more than $8.3 billion** in 2009 (HCUP, NIS, HCUP, AHRQ; 2009)

with a prosthesis. “The area really needs to be dry so they
need to be changing the underlying sock at least daily.
And then in the summer or if they’re doing activities that
lead to more perspiration, they should be changing the
underlying sock more frequently and carrying extra dry
linings with them. Then making sure that they’re using a
gentle cleanser and cleaning the limb, socket, and linings of
the prosthesis on a regular basis, and moisturizing. As the
skin becomes dry and irritated, repairing the barrier with a
bland, fragrance-free emollient makes a huge difference.”

Fit and daily care aside, “Botox is designed to reduce
sweating and that’s quite effective,” Dr. Meyerle said.
“We also do laser hair removal because we found that if
you can eliminate that excess hair, then that’s going to
decrease the amount of friction that you have and it also
decreases sweating.” Dr. Meyerle has also experimented
with injecting fibroblasts to change the skin at the stump
site to make it more like the skin on the soles of the feet.
However, those trials are in a holding pattern. “It works
in the lab, but getting the funds to do more studies is
challenging.”

Overall, Dr. Sheehan believes that there needs to be
more dermatologic involvement in the process of fitting
patients with prosthetics. “I think that if we can work
with the prosthetist and the amputee clinic as much as
possible there’s huge benefits to that. We can offer our
input on skin care and that definitely improves the patient
experience.” Dr. Meyerle agrees. “As a dermatologist,
we really are brought in late in the game. I don’t know if
that’s really the fault of anyone, but skin disease is a big
part of this and the reason that people are not wearing
their prostheses is because of the dermatitis.”

On the other side of the coin, for the everyday
practicing dermatologist, asking about a patient’s prosthetic
limb and potential skin-related complications is not always
part of the routine. “I think it’s just one of those things that
people don’t ask about. Dermatologists don’t necessarily
feel comfortable saying, ‘can you take off your leg for
me?’ Talking about people’s prosthesis: that’s a traumatic,
emotional thing for some people,” Dr. Meyerle said.
However, “If you don’t ask, they won’t tell you, and the
main goal is to prevent that dermatitis in the first place.”

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line of defense against the sun’s harmful UV rays.”

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BALANCE DUE

Practical strategies for dealing with high deductibles
While you didn’t go to medical school to learn about health insurance, you better know about it now. Understanding high-deductible health plans and having a system and policy in place to address them can make all the difference in getting paid for services rendered.

“Insurance has gotten very difficult for patients to understand,” said Gail LaBarr, the practice administrator for Marc Darst, MD, a dermatologist in private practice in Charlotte, North Carolina. Many patients have deductibles of $5,000 or higher, which basically means they’re paying out of pocket for a lot of services. They think their insurance covers more than it actually does. “It’s a challenge for the patient and the physician who is providing the services and needs to get paid in order to stay in business,” she added.

And it’s not just the billing and collections staff discussing high deductibles and other insurance issues with patients. “Five years ago, I never mentioned deductibles and co-insurance,” said Rutledge Forney, MD, who is in a group practice with five other dermatologists and two physician assistants in Atlanta. “I’ve had to learn about them not only for my patients, but also for my employees. Being a business owner and an employer has made me much more sophisticated in my knowledge of insurance and much more proactive in talking to my patients about these issues.”
All patients affected by high deductibles

Both the working poor with inexpensive insurance plans and individuals who earn a high wage with financial responsibility for their care are impacted by high deductibles. Neither group of patients have a clear understanding of just how much of the total bill they are responsible for, according to Rachna Chaudhari, MPH, the AAD’s senior manager of health technology, payment, and new practice models. That is why having a conversation ahead of time explaining what the services cost, how much the patient is expected to pay, and what is the patient’s deductible is essential, she said. It doesn’t have to be a detailed conversation about the levels of service; a general charge for a general procedure should suffice, Chaudhari noted. Having patients sign a policy form indicating their financial responsibility for payment can help reinforce the issue.

High earners, however, usually have a credit card, health savings account (HSA), or flexible spending account (FSA), all of which have their own rules and regulations. Some high-deductible plans offer different timelines for paying the deductible and some don’t allow the practice to collect payment using the HSA before the service is completed, she said. Usually using HSAs requires a lot of documentation with receipts. The staff must be knowledgeable about the different rules and regulations and be prepared to provide all of the necessary documentation.

The working poor with high deductibles seem to seek care only if they are truly desperate, said Ted Lain, MD, a dermatologist in private practice in Austin, Texas. “High earners with high deductibles seek care more frequently and earlier on,” he added, “but they still may seek care less often than if they had less financial responsibility at each visit.”

Collecting payment at the time of service

Collecting payment at the time of service and using practice management tools, such as real-time claims adjudication, are a necessity in today’s world of high deductibles. “The first thing dermatologists need to do is make sure they know what the patient’s deductible is even before the patient comes in for an appointment,” Chaudhari said. Using real-time claims adjudication helps determine what the patient owes at the time of service. It not only indicates the patient’s co-insurance or co-pay, but also the deductible and how much of it has been met. Increasingly more practice management systems offer this technology.

Next, dermatologists should develop a financial policy to address how they are going to collect payment. Should they collect half the payment before the services are provided and collect half afterward? Should they collect the full payment at the end of the visit? The AAD has published model policies in its Office Policy and Procedures Manual to help dermatologists determine the best policy for their practice.

“Surprisingly, some practices are still stuck in low-deductible think,” said Karen Zupko, President of Karen Zupko & Associates, Inc. “Practices should no longer wait to bill insurance first and send a statement to the patient weeks later. Patients should be asked to pay appropriate amounts they owe, at the time of service.” Additionally, practices should encourage patients to register via their patient portal, which is a very helpful tool for collecting insurance information before the patient arrives, Zupko said.

Approximately four years ago, Dr. Darst invested in a real-time adjudication program as an add-on to his existing practice management system that changed everything. “We know what each of our insurance contracts pay and what the allowable is,” LaBarr said. “We can figure out almost to the penny what the patient will owe us before he or she leaves the office.” Staff collects the co-pay before the appointment and collects payment for services rendered after the visit, depending on whether or not the patient has met the deductible. “We always collect the co-pays because that’s what’s going to pay the payroll,” she added.

When the patient arrives, staff still looks at the insurance card to check for pre-authorization. Many primary care physicians send enough prior authorizations for six months at a time when sending a patient for referral, LaBarr indicated. If the patient shows up without the required prior authorization, he or she is handed a telephone to call the primary care physician to obtain one. “Checking for prior authorization is an important part of making an
appointment because we don’t want the patient getting stuck with a bill that could have been avoided,” LaBarr said.

It’s especially important in January when health plans change their rules. She has seen plans start requiring prior authorization, limiting the health care systems at which patients can seek care, only paying for services provided by a physician and not a physician assistant, or offering a new insurance product with its own set of rules. This year, a South Carolina marketplace product no longer allowed members to come to North Carolina for care other than for emergency services, said LaBarr, explaining that the practice is located on the border of South Carolina. Often, it’s up to the staff to explain why the patients now have to pay out of pocket for services that were covered the previous year. “Every January, it takes us the first two months of the year to weed through the new products,” she said. LaBarr routinely updates a list of all the exceptions for staff.

Dr. Lain also uses real-time adjudication. All codes related to the patient’s visit are input prior to check-out, enabling staff to collect what the patient owes for the appointment. In addition, each insurance plan’s fee schedule is uploaded annually to the electronic health record.

At the Skin Surgery Center in North Carolina and Virginia, founded by Barry Leshin, MD, front desk staff verifies demographics and insurance; checks insurance eligibility; and collects any past due balances, co-payments, co-insurance, and deductibles at the time of service. “If a patient has questions regarding their bill, we will review the charges with the patient and explain the level of decision-making or expertise involved in determining a diagnosis and corresponding treatment plan and/or procedure,” said Jamie Hopkins, MBA, CMPE, director of practice operations at the Skin Surgery Center. A process of appeal or claim investigation is started immediately for all denials. “Once insurance has provided payment, we begin the process of sending patient statements and collection efforts,” she added.

While Dr. Forney doesn’t have a real-time adjudication program, she has implemented “a system” for handling patients with high-deductible plans. Two years ago, she started informing patients with high deductibles that they will likely get a bill for the services rendered. For an optional procedure, she explains that they may want to wait until they meet their deductible or they may want to call their insurance to find out how much it will cost. She then gives them the procedure code(s). “I tell the patient very specifically to not ask if the procedure is covered because it will be covered. The patient has to ask,
‘What will this cost me?’” Dr. Forney emphasized. For skin cancers, she encourages the patient to have the biopsy and then to discuss options based on the results. Only one person opted to wait to have a procedure done, she said.

For Mohs surgery patients, costs are estimated based on lesion size and location, among other variables; their deductible; and how much they have already met prior to the procedure being performed, Dr. Forney explained. Patients are asked to pre-pay for Mohs surgery.

Payment plans and other options
Payer contracts typically dictate the cost of services and how payments must be handled for patients in a particular health plan. Those rules and regulations can vary based on the insurance product, Chaudhari said. “That is why it’s so important for dermatologists to read through their contracts with all of their payers, insurers, and Medicare to make sure they’re not running afoul of any of those regulations,” she added. “They need to understand what is being asked of them in terms of high deductibles and the financial obligations of their patients.”

Many dermatologists are exploring whether they should offer a payment plan or other options, Chaudhari said. If they decide to offer a payment plan, they should develop policies to address each of the scenarios in which it would apply to ensure that all patients are being treated equally and fairly. It is prudent to have patients sign an agreement stipulating the details of the payment plan, she added.

The Skin Surgery Center offers same-day discounts, which do not go below the Medicare allowable, for uninsured or self-pay patients, Hopkins said. Sometimes, patients decide not to file insurance and become a self-pay patient instead. Those patients waive their right to file insurance, which they are told on the date of service. “We also offer a similar discount if the full amount is paid within 30 days,” she said. In addition, the center offers interest-free payment plans for all patients and charity care for those qualified patients who may have financial difficulties, Hopkins noted. The working poor with inexpensive insurance plans usually take advantage of the payment plan arrangements, which are made with the central billing office.

At Dr. Darst’s practice, staff has devised a self-pay fee schedule based on a mix of the different contractual agreements for uninsured patients. When explaining fees for services, LaBarr uses a car repair analogy. “You take your car in to get the oil changed but while you’re there, they notice the fan belt needs to be replaced,” she said. “If you’re coming in for a routine checkup, but the dermatologist sees something that looks suspicious, he may do a biopsy.” Patients often come in for one problem, she said, but during the appointment, they ask the doctor to look at a mole or rash, or they need their medications reviewed, all of which bumps up the level of service. On occasion, patients ask to do a monthly payment arrangement. “If they really need to be seen, but can’t pay for it,” LaBarr said “we will expect a certain amount the day of services and then do either a three- or five-month payment arrangement.”

Self-pay patients at Dr. Forney’s office are told the average cost of an office visit and that additional charges will be added to cover additional procedures if needed. Since she started in practice 14 years ago, Dr. Forney has offered a 30 percent discount to anyone who pays at the time of the visit. That includes patients who are insured, but decide not to file with their insurance because they know they will never reach the deductible. “If the patient pays me at the time of service, I’m all the better because I have to wait 30 to 90 days for the insurance companies to pay me,” she said. Some people choose to pre-pay a non-urgent procedure on a monthly basis until it’s paid off. “In effect, they put the surgery on layaway,” Dr. Forney said.

The bigger issue is people who want to set up a payment plan after they have the services and receive a large bill. Sending out a monthly statement costs at least $8, Dr. Forney said. She explains that the office will not bill the patient every month because it’s too costly, but as long as they make a monthly payment, the patient won’t be sent to a collections agency. “I had one patient who faithfully paid me $5 a month for five years,” she said. Depending on a patient’s circumstances, the Mohs surgeon has taken one-third
Whether it’s a teenager with acne, a young adult with an eczema flare-up, or a mom with skin cancer, high self-pay costs can be a barrier to treatment. The CareCredit healthcare credit card with promotional financing options gives patients a financial resource that’s always there to pay for:

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of the payment ahead of time, one-third on the day of the procedure, and one-third afterward.

**Price reduction please**

“As insurance deductibles go up and up, everybody is asking about a price reduction,” LaBarr said. She explains that the practice has a contractual obligation to the insurance company to charge the allowable for the services akin to the patient’s contractual arrangement to pay for those services.

For insured patients, dermatologists have to charge the fee that the insurance contract dictates, so they wouldn’t be able to reduce the fee if they’re within the parameters of what the contract says, Chaudhari noted. For uninsured patients, Zupko recommends that the practice use the current Federal Poverty Guidelines to determine if the patient qualifies for a fee reduction. “There can be no charge of discrimination if you use these criteria,” she said. Another option is to charge the uninsured patient the allowable amount from Medicare or a similar plan as it is a standard amount that can be referenced.

The payment policy that Dr. Lain uses very clearly states the practice’s legally binding contractual agreement with each patient’s insurance company. In addition, there are signs posted in each exam room stating that all procedures are considered “surgery” by insurance companies and may apply to the deductible, apart from the office visit. “If a patient asks about the cost of a certain procedure, we will check that prior to performing the procedure,” he said.

**Impact on patient compliance**

High deductibles impact patient compliance primarily because patients are not filling their prescriptions. The Academy is advocating for lower drug prices to ease patients’ financial burden, Chaudhari said. In the meantime, it’s very frustrating for dermatologists. “They are trying to treat their patients as best they can, but the patients are unable to afford the required treatment,” she added.

The doctor tries to prescribe the most economical medications to meet the patients’ needs, LaBarr said. “But we still have patients who call back and say they can’t afford any of them.” Samples only go so far, especially for patients who need to be on a medication long term. Consequently, the nurse spends a lot of time trying to track down affordable medications and she has become very good at it, LaBarr added. The problem is exacerbated in January when the new deductible kicks in and patients have to pay down the deductible before insurance will pay for medications; they can’t even use coupons, she said.

The prices on generic medications have become so outrageous that Dr. Forney has started prescribing the brand name drugs that, in many cases, patients can purchase for less. Most brand name drugs have a cash-pay price, which may be significantly less than what the patient would have to pay with insurance, she said. Dr. Forney has also directed patients to check prices on GoodRx.com.

“Pharmacy deductibles often dictate the medications I am able to prescribe, and many patients will modulate the frequency of use, or the amount used, of the medication in order to extend its life,” Dr. Lain said.

Patients are not keeping follow-up appointments, either. “They know they already have a balance and they don’t want to incur an additional balance,” Dr. Forney said. Patients who make a follow-up appointment for a non-urgent diagnosis are less likely to return if they think they will incur additional costs, Hopkins noted. Additionally, if the issue has improved or resolved, patients often don’t return for follow-up. If a patient comes in for a specific issue, but really needs to come back for a full skin exam, LaBarr said, they will schedule an appointment but then cancel it.

Additionally, patients are not following up with recommended care. “The worst thing for us is people who don’t follow up on a pre-malignant or malignant lesion because they can’t afford to,” Dr. Forney said. In Fulton County where her practice is located, there is a good public hospital with a good dermatology department where the patients can go for the rest of their treatment. There is also a VA Medical Center for veterans. “But we have a medico-legal responsibility to make sure they understand the impact of their actions,” Dr. Forney said. LaBarr is responsible for writing letters to patients who are non-compliant. Basically, the letter relays the doctor’s concern for the patient’s health and urges the patient to follow-up with the recommended care. It’s a lot more work for the physician to follow up with non-compliant patients, she added.

Dr. Lain points out that there is a balance between the benefits of more personal financial responsibility for medical care leading to less overuse and the high cost of medical care causing patients with high deductibles to avoid care when needed. “The current state of our medical system has not achieved an equitable relationship between these two opposing forces,” he concludes, “causing the physician-patient relationship to be clouded by financial uncertainty.” dw
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Giving research a boost

BY HENRY W. LIM, MD

It’s hard to miss the constant push and pull in health care these days. There has been a lot of discussion surrounding various health care issues at the state and federal levels and among legislative and regulatory bodies. For many of these issues, not everyone is in agreement. From health care reform to managing drug costs, there is no shortage of debate among policymakers and within the public. There is one issue, however, that most of us can get behind: the value of medical research.

As dermatologists, we know the positive effects breakthrough medical research can have on our patients. For example, in the biologics sphere alone we have made exceptional strides in researching and developing treatments for a number of conditions such as psoriasis, hidradenitis suppurativa, chronic urticaria, vitiligo, dermatomyositis, and alopecia areata. Most recently, we’re seeing movement on the atopic dermatitis front, with the recent U.S. Food and Drug Administration (FDA) approval of the biologic, dupilumab, and a topical PDE-4 inhibitor, crisaborole. In fact, so far in 2017, the FDA has approved 26 new drugs for sale, including other dermatology medications such as avelumab for metastatic Merkel cell carcinoma and brodalumab and guselkumab for psoriasis. For our patients, these new treatments, and the breakthrough research that pushed these drugs over the finish line and into the hands of consumers, has made all the difference.

Clearly, there is great news in the world of medical research. Medical research funding is following suit. The Cures Act, also known as the 21st Century Cures Act, passed both the U.S. House of Representatives and Senate in December and former President Barack Obama signed the legislation into law on Dec. 13, 2016. The Cures Act allocates $4.8 billion in new funding for the National Institutes of Health (NIH) — of which $1.8 billion will go toward the Cancer Moonshot program for cancer research. Additionally, the Cures Act allocated $500 million for the FDA in an effort to facilitate the increase in the number of new drug approvals.

Although we have achieved great successes in boosting medical research funding, we need to continue to push for more. For Fiscal Year (FY) 2018, the American Academy of Dermatology Association (AADA) has requested that Congress increase funding for the NIH by $2 billion above final FY 2017 funding — including proportional increases for the National Cancer Institute (NCI) and the National Institute of Arthritis, Musculoskeletal and Skin Diseases (NIAMS). Additionally, the AADA is calling on Congress to include $5 million for the National Skin Cancer Prevention Education Program at the Centers for Disease Control and Prevention in the FY 2018 budget. The Academy is not alone in this endeavor; the Academy is an active member of the One Voice Against Cancer (OVAC) coalition — which support NIH and NCI funding — and is also a member of the NIAMS Coalition, which supports NIAMS funding.

We know that medical research is a critical component of improving patient care, and our patients know that breakthrough treatments can be life changing. However, we need to ensure that we continue to take the long view on this issue. Rest assured, your Academy will not ease up on this essential priority and will continue to stress to policymakers that funding medical research now will generate positive outcomes for patients in the future. dw

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Grants available for technology-based teaching applications

Letters of Intent due Nov. 15, 2017

The AAD’s Sulzberger Institute for Dermatologic Education Committee is seeking grant proposals for technology-based teaching applications that further education in dermatology and dermatologic surgery. A two-stage process will be employed. In the first stage, applicants will submit an online Letter of Intent (LOI). If the LOI is selected by the committee, the applicant will be invited to move forward to the second stage and submit a full proposal. The deadline to submit the LOI is Nov. 15, 2017.

Applicants will be notified in December 2017 if their LOI was accepted and if a full proposal will be requested by the Committee.

Proposals from individuals with a clear association to dermatologic organizations will be given preference; however, all proposals to develop technology for dermatology education will be considered. Successful applicants will be notified by April 2018.

Grants are available in the following categories:

- Seed grants (up to $30,000 per year) for a period of one to two years
- Small grants (up to $5,000) for a period of one year

The Committee has established the following criteria for evaluation of the proposals:

- Perceived value of the project to dermatologic education;
- Practical and innovative use of audiovisual and technology methods within the scope of the proposal;
- Clarity and completeness of the project abstract; and
- Willingness to grant the American Academy of Dermatology the right of first refusal to partner with the grant recipient in the development and marketing of any potential products which may result from the research effort.

For more information, contact Margaret Singer, education coordinator, at msinger@aad.org or visit www.aad.org/sulzberger.

Academy seeks assistant secretary-treasurer nominees

Applications and nominations are now being solicited for the position of assistant secretary-treasurer for the American Academy of Dermatology and AAD Association. The term begins March 2019. Marta J. Van Beek, MD, MPH, is the current Assistant Secretary-Treasurer.

Members interested in serving the Academy in this position should have significant administrative and financial management experience. The position of assistant secretary-treasurer requires a considerable time commitment. Applicants must be able to serve for six years: three years as assistant secretary-treasurer and three additional years as secretary-treasurer.

To learn more about the position and apply, visit www.aad.org/AST. Applications are due Jan. 5, 2018. Questions may be directed to Cyndi Del Bocco in the AAD Executive Office at (847) 240-1041 or cdelbocco@aad.org.
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Camp Discovery: making the outdoors great again

BY EMILY MARGOSIAN, CONTENT SPECIALIST

For nearly 25 years, kids with chronic skin conditions have had the opportunity to swim, go horseback riding, fish, and more — all at no cost to them, thanks to the AAD’s Camp Discovery program. Every year since 1993, over 300 campers have had the chance to meet other children with similar skin conditions, experience new activities, build independence, and form lifelong friendships. Staffed in part by dermatologists, residents, pediatricians, physician assistants, nurses, and other volunteers with chronic skin conditions, Camp Discovery provides a safe and inclusive environment for good old-fashioned outdoor fun. To learn more or make a donation to support Camp Discovery, visit www.aad.org/public/kids/camp-discovery. dw
Upcoming CME Activities

Basal Cell and Squamous Cell Cancer Dermatopathology and Fundamentals of Mohs Surgery

DoubleTree Hotel San Diego, Mission Valley – San Diego, CA

November 7-8, 2017 – Basal Cell and Squamous Cell Cancer Dermatopathology
- Introductory (Day 1) and Advanced (Day 2) discussions
- Pure pathology approach to understanding BCC and SCC characteristics
- Examination of reactive changes commonly visualized at biopsy sites
- Identification of non-BCC and non-SCC structures in Mohs-excised tissue

November 9-12, 2017 – Fundamentals of Mohs Surgery
- Basic Mohs surgical, histopathologic, and laboratory skills for physicians and technicians
- Practice efficiencies including office/laboratory design, management of patient flow and tissue specimen transfer
- Appropriate indications for Mohs, based on histologic subtype and anatomic location
- Critical mapping considerations for proper orientation, correlation of histologic findings to surgical wound
- Multiple microscope laboratory sessions featuring small group and independent Mohs case reviews

ASMS Annual Meeting and Focus on Skin Cancer

Location – TBD

May 24-27, 2018 – Dermatologic Surgery: Focus on Skin Cancer
- Current topics for dermatologic surgeons and cutaneous oncologists at all levels of training and experience
- Expert panel discussions: complex closure approaches, melanoma treatment options and management of other challenging tumors
- Review of dermoscopy advances in melanoma diagnosis
- Comprehensive literature reviews
- Small-group histopathology discussions; Mohs and non-Mohs cases available for review

For additional information regarding ASMS educational activities, membership opportunities, and patient resources, please contact:

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