Delays in melanoma surgery may vary by insurance type, according to research in *JAMA Dermatology*.

While Medicaid patients had the highest likelihood of delays, significant proportions of Medicare and privately insured patients also experienced delayed care. Also, the likelihood of surgical delay was lower if the physician performing the operation or the clinician making the diagnosis was a dermatologist, according to the results.

Researchers led by Adewole S. Adamson, MD, MPP, of the University of North Carolina at Chapel Hill, used data from the North Carolina Cancer Registry linked to administrative claims from Medicare, Medicaid and private insurance.

The study included 7,629 patients (48 percent insured by Medicare, 48 percent by private insurance and 4 percent by Medicaid). Surgical delay was defined as surgical removal more than six weeks after melanoma diagnosis. Study limitations include that patients were exclusively from North Carolina.

“Delays in melanoma care could be reduced through better access to specialty care and cross-disciplinary partnerships to ensure that patients can safely navigate the treatment episode. Understanding why Medicaid patients receive less timely care for melanoma should be given further scrutiny,” the article concludes.

A second study identified disparities in eczema care, this time linked to race. White children in the US are more likely to see a doctor for treatment of eczema than black children, despite the fact that the disease is likely more severe among minorities, research from the Perelman School of Medicine at the University of Pennsylvania found. In fact, black children with eczema were 30 percent less likely to see a doctor for their eczema than white children.

The study, published in the *Journal of the American Academy of Dermatology*, also found black children who see a doctor about the condition have more visits and receive more prescriptions than white children, indicating more severe disease.

Data from the Centers for Disease Control shows roughly 11 percent of children experience eczema in the United States, with black children experiencing it more commonly (17.1 percent) than white children (11.2 percent) or Hispanic children (13.7 percent). In addition to the physical impact on the skin, eczema is associated with negative psychological effects.

“Previous studies have demonstrated disparities in overall healthcare utilization among racial and ethnic minorities, but few studies have examined this question specifically for eczema,” says the study’s senior author Junko Takeshita, MD, PhD, MSCE, an assistant professor of Dermatology and Epidemiology at Penn, in a news release. “This is the first study to look at racial and ethnic differences in healthcare utilization for eczema on an individual level rather than relying on a sample of outpatient visits, making this a unique evaluation of eczema that includes those not accessing care for their disease.”

The researchers gathered data from the Medical Expenditure Panel Survey, the most complete source of data currently available on healthcare utilization, cost, and insurance coverage in the United States. All of the information is self- or caregiver-reported over a series of interviews, and is designed to be representative of the general population. The team used information from 2001 through 2013 for Americans under the age of 18 who identified themselves as white, black, or Hispanic. Those who identified in other groups did not make up a large enough sample for evaluation.

Based on data collected from 2,043 people with eczema, researchers estimated the data on a national scale. According to these estimates, of the nearly three million children with eczema represented in this study, 66 percent are white, 18 percent are black, and 16 percent are Hispanic. Overall, roughly 60 percent of these children have seen a doctor for their condition, but the percentages vary by race. Among white children, 62.1 percent saw a doctor. A similar proportion of Hispanic children (58.1 percent) saw a doctor for their eczema. However, the number dropped to just 51.9 percent for black children which, after accounting for baseline differences in sociodemographic factors and insurance status, translates to a 30 percent lower likelihood of seeing a doctor for their eczema than whites.

“Data show that race alone can be a predictor of whether or not a child with eczema will see a doctor, independent of other social or demographic factors or insurance status,” Takeshita says.

In addition, minority children reporting eczema were an average of a year to a year and a half younger than white children. They were also less likely to have any private insurance, more likely to fall into the low income category, and more likely to have asthma relative to white children.
FDA Adds Forehead Lines Indication for Botox Cosmetic

Allergan plc’s Botox Cosmetic received its third FDA indication: the temporary improvement in the appearance of moderate to severe forehead lines associated with frontalis muscle activity in adults. This approval makes the brand the first and only neurotoxin indicated for three facial treatment areas—forehead lines, crow’s feet lines, and glabellar lines. Botox Cosmetic is also the only neurotoxin brand to receive approval for aesthetic indications beyond glabellar lines in the US.

In clinical trials, Botox Cosmetic demonstrated efficacy compared with placebo in the reduction of the severity of forehead lines, as assessed by both the investigator and the subject at Day 30 (primary endpoint): 61 percent of subjects in study one and 46 percent of subjects in study two met the primary endpoint compared with placebo (0 percent in Study one and one percent in Study two). Similar response rates were seen across three treatments cycles with Botox Cosmetic.

Hair Restoration On the Rise: ISHRS

The worldwide volume of surgical hair restoration procedures performed from 2014 to 2016 rose 60 percent, with 635,189 procedures performed worldwide in 2016, according to the latest statistics from the International Society of Hair Restoration Surgery.

“Like other forms of cosmetic surgery that can boost self-confidence and self-image, people increasingly are more open to talking about having hair transplantation and with that word is spreading how one can achieve permanent, natural-looking results with this proven surgical procedure,” says Ken Washenik, MD, PhD, FISHRS, president of the ISHRS and the Medical Director of Bosley and the Chief Executive Officer of the Adierans Research Institute, a biotechnology firm involved in researching tissue engineered hair follicle neogenesis and cellular based hair restoration, in Beverly Hills, CA. “In recent years, we have noticed a surge in physicians registering for our annual congresses to learn the procedure, and some techniques have helped newer physicians to the field perform the procedure with greater ease. More educated physicians translates to better results for patients, which I believe is the reason we’re noticing such an increase in the number of procedures taking place.”

Two-Year Data: Tremfya Achieves Consistent Rates of Skin Clearance in Moderate to Severe Plaque Psoriasis

New longer-term data from the open-label extension of the VOYAGE 1 trial demonstrate consistent rates of skin clearance with Tremfya (guselkumab) treatment through week 100 among patients with moderate to severe plaque psoriasis receiving the subcutaneously administered anti-interleukin (IL)-23 monoclonal antibody. The longer-term findings from the Phase 3 VOYAGE 1 study, which were presented by Janssen Research & Development, LLC at the 26th European Academy of Dermatology and Venereology (EADV)
Congress, showed more than 80 percent of patients receiving Tremfya, including those initially treated with placebo or the anti-tumor necrosis factor (TNF)-alpha agent Humira (adalimumab) achieved at least a 90 percent improvement in the Psoriasis Area Severity Index (PASI 90), or near complete skin clearance, and an Investigator’s Global Assessment (IGA) score of cleared (0) or minimal disease (1) at week 100. The findings, presented during an EADV late-breaker session, follow the recent European Medicines Agency’s Committee for Medicinal Products for Human Use (CHMP) recommendation for approval of Tremfya, and the United States Food and Drug Administration (FDA) approval of Tremfya in July.

Positive Study Results for Dupixent in Patients With Moderate to Severe AD

Dupixent (dupilumab) with topical corticosteroids (TCS) significantly improved measures of overall disease severity, skin clearing, itching, and patient reported quality of life measure in adults with moderate-to-severe atopic dermatitis (AD) who are inadequately controlled or intolerant to cyclosporine A (CSA), or when this treatment is medically inadvisable, according to results from the Phase 3 CAFÉ study.

Regeneron and Sanofi’s Dupixent is a human monoclonal antibody that is designed to specifically inhibit overactive signaling of two key proteins, IL-4 and IL-13, which are believed to be major drivers of the persistent underlying inflammation in AD.

The results of this study are being presented at the European Academy of Dermatology and Venerology (EADV) Congress in Geneva, Switzerland.

A total of 325 patients in Europe were randomized into three treatment groups in the 16-week study to receive either Dupixent 300 mg weekly with TCS, Dupixent 300 mg every two weeks with TCS or placebo with TCS. The primary endpoint of the study was the proportion of patients that achieved a 75 percent or greater improvement in the Eczema Area and Severity Index (EASI-75) score at 16 weeks from baseline.

Fifty-nine percent of patients who received Dupixent weekly with TCS, and 63 percent of patients who received Dupixent every two weeks with TCS achieved EASI-75, compared to 30 percent of those patients who received placebo with TCS.

The mean percent change improvement in EASI from baseline at 16 weeks (a secondary endpoint) was 78 percent and 80 percent for patients who received Dupixent weekly or every two weeks with TCS, respectively, compared to 47 percent for those who received placebo plus TCS.

BY THE NUMBERS

80 Percentage of dermatologists who believe women often focus on facial skincare but neglect body skincare, according to new research from Dove. Additionally, 69 percent of dermatologists report that many women use gentle facial cleansers but use harsh soap on the rest of their body and don’t realize the damage they may be doing to their skin in the shower. Fully 86 percent of dermatologists agree that women should be more conscious of the effects of using harsh cleansers on their body.
Take 5

TIMOTHY J. MILLER, PH.D., CEO AND PRESIDENT, ABEONA THERAPEUTICS INC.

Abeona CEO takes on the worst disease you’ve never heard of.

Epidermolysis Bullosa (EB) has been called “the worst disease you’ve never heard of” with good reason. This rare inherited connective tissue disorder affects one of every 20,000 births in the United States, and approximately 200 children a year are born with EB, according to The Dystrophic Epidermolysis Bullosa Research Association of America (debra of America). There is no treatment or cure for EB, and that is where Timothy J. Miller, PhD, Chief Executive Officer and President of Abeona Therapeutics Inc., and team come in.

Abeona was founded with a mandate to develop technologies and products aimed at curing various rare diseases. In dermatology, these diseases include Epidermolysis Bullosa and Recessive Dystrophic Epidermolysis Bullosa (RDEB). EB patients lack functional type VII collagen owing to mutations in the gene COL7A1 that encodes for C7, which is the main component of anchoring fibrils that attach the dermis to the epidermis.

FILLING AN UNMET NEED

“Recessive Dystrophic EB or “butterfly skin” syndrome is the most devastating form of EB. Skin can be ripped off during something as gentle as a newborn ink-blot test on the foot. A little girl with EB once told us she was afraid to wake up because she feared her clothing would be stuck to her. She would have to soak the area in olive oil just to get her clothing off as you can’t rip at them without tearing skin. Until now, the only option has been palliative care to keep the wounds moist, pain medications and bandages. Families can spend thousands of dollars on bandages alone. EB patients live in pain 24/7, 365 days a year. Infection is common in open wounds and the constant scarring and healing increases risk for squamous cell carcinoma.”

GENE INTEGRATION STRATEGY

“The EB-101 product is a gene integration strategy, where a patient’s own keratinocytes are genetically corrected to remove the underlying cause of the disease, the COL7A1 deficit. It is the only therapy in the world that corrects the underlying gene defect causing EB.”

BREAKTHROUGH STATUS

“The FDA recently granted us Breakthrough Therapy design- nation for EB-101, which enables priority review and expedites the approval process. This is the first Breakthrough Therapy designation for Abeona since the FDA initiated the program in 2013. So instead of 60-75 days for review, the designation enables EB-101 to have a much shorter review period. This affirms that the FDA believes we have a promising approach to treating EB. We anticipate initiating the Phase 3 trial in the first quarter of 2018 and plan to enroll 10-12 patients.”

GENE INTEGRATION STRATEGY

“The EB-101 product is a gene integration strategy, where a patient’s own keratinocytes are genetically corrected to remove the underlying cause of the disease, the COL7A1 deficit. It is the only therapy in the world that corrects the underlying gene defect causing EB.”

BREAKTHROUGH STATUS

“The FDA recently granted us Breakthrough Therapy design- nation for EB-101, which enables priority review and expedites the approval process. This is the first Breakthrough Therapy designation for Abeona since the FDA initiated the program in 2013. So instead of 60-75 days for review, the designation enables EB-101 to have a much shorter review period. This affirms that the FDA believes we have a promising approach to treating EB. We anticipate initiating the Phase 3 trial in the first quarter of 2018 and plan to enroll 10-12 patients.”

PROMISING PROTOCOL

“Patients undergo a biopsy, and the cells are sent to the manufacturing facility to separate, correct and expand keratinocytes. When the EB-101-corrected skin cells are applied to the patient’s wounds, the cells are able to function correctly and help the skin “stick” to the body. Patients come back for additional EB-101 treatments to cover more wounds on their body. We treat a certain percentage of the skin at one time, approximately six grafts which is about the size of an iPhone 6-plus and can cover most of a limb. After treatment, the wound is closed and patients report less pain and itching and improved quality of life.”

EXCITING RESULTS

“Studies of EB-101 showed wound healing of greater than 50 percent for more than two years. Secondary endpoints included expression of collagen C7 and restoration of anchoring fibrils at three and six-months post-administration.

Specifically, wound healing, defined as >50 percent closure after EB-101 administration, was observed in:

- 100 percent (36/36 treated wounds, n=6 subjects) at three months;
- 89 percent (32/36 treated wounds, n=6 subjects) at 6 months;
- 83 percent (20/24 treated wounds, n=4 subjects) at 12 months;
- 88 percent (21/24 treated wounds, n=4 subjects) at 24 months;
- 100 percent (6/6 treated wounds, n=1 subject) at 36 months post-administration.”

C7 and morphologically normal NC2 reactive anchoring fibrils were observed in EB-101 treated wounds up to two years post-administration. The data was presented at the (Continued on page 18)
Moreover, data from a supportive natural history study of 1,436 wounds from 128 patients with RDEB showed that when 13 RDEB patients with a total of 15 chronic wounds were treated with an allograft product, including Apligraf and Dermagraft, only seven percent (1/15 treated wounds) remained healed after 12 weeks, and 0 percent (0/15 treated wounds) remained healed after 24 weeks. This is a meaningful finding because there are no approved therapies for RDEB patients that demonstrate significant wound closure after two months post-application.

I really enjoyed the editorial by Joel Schlessinger, MD, “Reflections on 25 Years of Private Practice” in the June edition of Practical Dermatology® (available online at PracticalDermatology.com/2017/06)!

Here are some random pearls from my 15 years in practice:

Sit down and talk to patients, literally eye to eye; avoid standing over the patient.

There is a magical quality to fresh baked chocolate chip cookies served to patients, and the aroma melts everyone’s heart.

A Keurig coffee maker is probably the best “device” physicians can have in their offices.

Consider having a five- to 10-minute staff meeting once a week where all staff are kept accountable for specific goals (related to efficiency, patient service, patient care, billing, etc.). Document these on a whiteboard displayed in the kitchen/break room. Everyone, including the doctor, declares at the next meeting whether they achieved the goal or not, and they then produce another set of small goals for next week.

Consider selling generic medications in the practice (i.e., topical and oral antibiotics), if permitted by law. Patients will be grateful for the convenience, especially after surgery.

Consider using the unused absorbable dyed sutures for your top epidermal sutures. The savings are significant over time.

Handwrite a thank you note to each staff member at the time of her/his bonus(es); highlight why you specifically enjoy working with her/him.

Personally call post-op patients two days after their surgery. Avoid calling the night of or the next day when all they will talk about is their pain. Prepare them with a good post-op “expectations” sheet that addresses pain.

Two Tylenol and two Advil taken together is essentially equivalent to one Vicodin.

Give out your cell phone number on your practice card. In my experience patients will rarely if ever call you, but the gained trust, reassurance, and your availability will pay dividends.

Consider creating a post-op goodie bag, including Vaseline, nonstick gauze, paper tape, and instructions.

—Adam Rotunda, MD, FAAD
Newport Beach, CA

I wanted to submit a correction to the article “Dermatologists Are Taking Action in Their Fight Against MOC” in the August 2017 issue (Available online at PracticalDermatology.com/2017/08).

Time limited certification began for those of us who completed our residency in 1991. I am in this group, and have taken my board examination, and passed it, three times. I am certainly not looking forward to the time, preparation, and cost of retaking my board exam a fourth time.

I also agree that the grandfather clause is contradictory to the underlying purpose of MOC and that all practicing physicians should be required to participate.

I hope that the MOC process will become more simplified and less onerous.

—Elena Martinho, MD, FAAD
Templeton, CA