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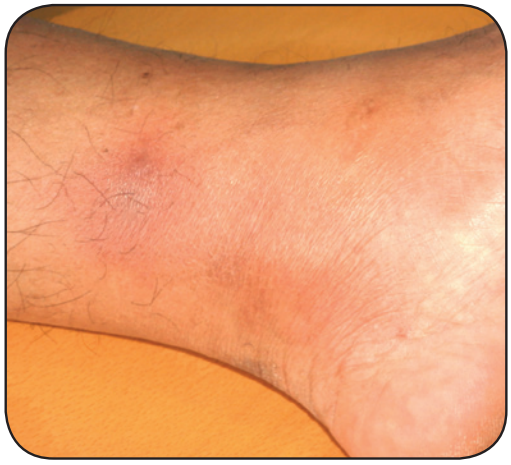
# JDPA

Journal of Dermatology for Physician Assistants







Official Journal of the Society of Dermatology Physician Assistants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SOCIETY OF DERMATOLOGY PHYSICIAN ASSISTANTS
SDPA
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JDPA Journal of Dermatology for Physician Assistants



**EDITORIAL MISSION:** The JDPA is the official clinical journal of the Society of Dermatology Physician Assistants. The mission of the JDPA is to improve dermatological patient care by publishing the most innovative, timely, practice-proven educational information available for the physician assistant profession.

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## *Finding Your Voice and Trusting Your Gut – It Takes Concerted Effort and Time*

When you are starting out as a new PA there is always so much to take in and learn. I remember my first year as a new PA keeping a lengthy daily log of all the diagnoses and health care topics that I needed to look up each night after clinic. I wanted to learn everything I could each night so that I would be even more prepared for clinic the next day. Fast-forward twenty years later, and not much has changed. While my daily lists are not nearly quite as long, I am still jotting down topics (e.g., new therapies, rare diagnoses I had not yet seen, new health care legislation, etc) that are important for me to further study in order to provide my patients I serve with optimal care.

Something that has changed over the course of my career is my comfort level in listening to my gut when something just doesn't add up. I have learned that regardless of how much dermatologic knowledge you have, trusting that little voice inside your head that tells you to look further, to question, to find your voice at times is as much an asset to making good clinical decisions as is staying up to date with the latest changes in healthcare. People say that with age comes wisdom, but I think that with age what I have come to value the most is having clinical confidence. Having the confidence to speak up and question has proven to be invaluable in the clinic setting.

It is important to listen to our inner voices, our intuitive responses, telling us to explore more, to dig deeper, and to not settle. It takes a concerted effort to continue learning and time to trust in our clinical intuitions. Always remember that we are our patients' advocates. It is our responsibility to provide the best treatment and care we possibly can. To optimally do so will require us to find the balance between striving to learn more and trusting our gut.

Travis Hayden, MPAS, PA-C
JDPA Editor in Chief
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# CALENDAR OF EVENTS

## 2018

### NOVEMBER

SDPA 16th Annual Fall Dermatology Conference
November 1 - 4, 2018
Loews Portofino Bay Hotel
Orlando, FL

## 2019

### MARCH

77th AAD Annual Academy Meeting
March 1 - 5, 2019
Washington, DC

### JUNE

SDPA Summer Dermatology Conference
June 5 - 9, 2019
Marriott Marquis
Washington, DC

### JULY

AAD Summer Meeting
July 25 - 28, 2019
New York, NY

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# FROM THE SDPA
## NEWS & CURRENT AFFAIRS

Dear Colleagues,

One of the primary goals of the SDPA leadership is to plan and prepare for the future of the Society. Recently your leadership team attended our annual leadership summit; there we brainstormed updates to the SDPA's strategic plan in an effort not only to secure the future of the Society, but to continue the advancement of the dermatology PA profession as well. Utilizing our mission to Empower, Educate and Advance dermatology PAs, the SDPA will remain focused on Education, Coalition Building, Membership Growth, Brand- Image-Visibility, Professional Development, and Advocacy and Legislative Monitoring.

As you know, education is one of the SDPA's primary focuses and we're excited that the Diplomate Fellowship program was released in June 2017. The program represents the highest standards in education for dermatology PAs. The final phase will be released in the coming weeks and I hope you will join me, and the over 1,300 others currently enrolled in the program, to become an SDPA Diplomate Fellow. Program graduates will be distinguished for their knowledge and the skills necessary to provide exceptional patient care while we collaborate as part of the dermatology team. Not only will you receive over 65 + CME credit hours, additional benefits will be available to Diplomate Fellows including invitations to special receptions at our conferences, discounts on conference registrations, and membership dues just to name a few!

Next year, 2019 will mark the 25th year of the founding of the SDPA. If you don't know the story, it involves our founder, Joe Monroe, standing in front of an AAD meeting in 1994 with a sign asking for other PAs to identify themselves. This resulted in a small group forming the basis of what would become the SDPA over pizza in Joe's hotel room. We've come a long way since that first meeting. The determined efforts of leaders have grown the Society into the largest and most advanced PA specialty organization in the nation. Mark your calendars now for a special 25th SDPA anniversary celebration during the SDPA Annual Summer Conference June 5-9, 2019 in Washington, DC.

As much as education is vital to our organization, it is only a part of the vast array of work the SDPA does to empower our members and to advance our profession. Now more than ever, advocacy and legislation are vital to the progressive growth of our profession. Make your voice heard and join the AAPA and the SDPA for a legislative fly-in on Wednesday, June 5th, 2019 in Washington, D.C. as we kick off the summer conference. This is our time to discuss with the legislators the issues that have an impact on the PA profession at large, our patients, and the impact on our ability to practice.

As part of our advocacy efforts, the SDPA has committed additional resources and efforts on behalf of our members to promote dermatology PAs and emphasize the importance we play in improving quality and timely access to patient care. You'll begin to see the results of these efforts in the near future. As part of these efforts, we will continue to partner with the AAPA as we advocate for and promote Optimal Team Practice (OTP) at the state level.

The overall value of your SDPA membership is immeasurable and I thank you for your dedication to our profession and the patients we all serve. When you have the opportunity, please take the time to show your appreciation for those current and past SDPA leaders who have paved the way for our organization to be the largest and greatest PA specialty organization in the nation!

Sincerely,

Joleen M. Volz

Joleen M. Volz, MPAS, PA-C, DFAAPA
SDPA President

# Dermatology Market Watch

## Ortho Dermatologics Announces 2018 Aspire Higher Scholarship Recipients

*Scholarships Awarded to Nine Students Affected by Dermatologic Conditions*

Ortho Dermatologics recently announced the 2018 honorees of the Aspire Higher program, which since 2013 has granted more than $450,000 in scholarships to students who have been affected by dermatologic conditions. This year nine students will receive scholarships of $10,000 each to pursue graduate or undergraduate degrees at an accredited, nonprofit, two- or four-year college, university, or advanced (post-high school) vocational or technical school.

"At Ortho Dermatologics, we understand that there is more to skin conditions than what meets the eye, and managing them often comes with challenges. We're proud to continue the Aspire Higher program to help students who have faced such challenges reach their educational goals, while also recognizing the positive impact dermatologists have had on their lives," said Bill Humphries, president, Ortho Dermatologics.

The 2018 honorees were selected from nearly 1,200 applications, based in part on essays sharing their experience of living with a dermatologic condition, as well as the role that a dermatologist, physician assistant, or nurse practitioner has played in helping treat it. The applications were judged by an independent panel of dermatologists from across the country.

"In the six years that I have served on the judging panel for the Aspire Higher program, I continue to be inspired by these students' dedication to education and passion to excel in their future careers," said Jonathan S. Weiss, M.D., dermatologist at Gwinnett Dermatology, Snellville, GA. "This is one of the most outstanding initiatives taking place in the dermatology community, and I am proud to join Ortho Dermatologics to help these outstanding students achieve their educational dreams and continue aspiring higher."

The Aspire Higher program recognizes students at varying stages of their educational careers through scholarships in three categories, including the Undergraduate Scholar Awards for those pursuing undergraduate degrees, the Graduate Scholar Awards for those pursuing graduate degrees, and the Today's Woman Scholar Awards for mothers pursuing undergraduate or graduate degrees.

The 2018 Aspire Higher recipients include:

**UNDERGRADUATE SCHOLAR AWARD**

- Jayla Chanel Davis, Alabaster, AL – University of South Alabama
- Daisy Pena, San Jose, CA – California State University Long Beach
- Mary Margaret Jordan, Melissa, TX – Baylor University

**GRADUATE SCHOLAR AWARD**

- Zoe Smith, Ferndale, MI – Wayne State School of Medicine
- Niki Vora, Buena Park, CA – UC Berkeley - UCSF Joint Medical Program
- Caitlin Parker, Taylorsville, UT – Roseman University of Health Sciences - College of Dental Medicine

**TODAY'S WOMAN SCHOLAR AWARD**

- Laura Lukens, Evanston, IL – Northwestern University - Kellogg School of Management
- Elizabeth Hendrix, Holladay, UT – University of Utah
- Jennifer Hurley, Hammonton, NJ – Fairleigh Dickinson University

"With the generous help of Ortho Dermatologics and the Aspire Higher scholarship program, I'm thrilled to continue my education at California State University Long Beach," said Daisy Pena. "It is wonderful that this program exists to help those who have struggled with their skin accomplish their academic goals – and I look forward to taking full advantage of this incredible opportunity while also raising awareness of skin conditions like alopecia."

To learn more about the Aspire Higher scholarship, please visit www.AspireHigherScholarships.com. The 2019 Aspire Higher scholarship program will begin accepting applications in early 2019.

*Since 2013, the Aspire Higher scholarship program has awarded 32 scholarships, which gave students a total of more than $450,000 toward their higher education on campuses nationwide. Ortho Dermatologics also matches donations to help children with chronic skin conditions enjoy a week of fun and adventure at the American Academy of Dermatology's Camp Discovery. The Aspire Higher Scholarship program is funded through the Bausch Foundation, which was established in 2017 to improve the lives of patients globally by providing access to safe, effective medicines, and by financially supporting health care education and causes around the world.*

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# Making college dreams come true

As part of its commitment to the dermatology community, Ortho Dermatologics created the Aspire Higher scholarship program. The program sponsors scholarships for new college students, graduate students, and mothers returning to college. Patients who have been treated for skin conditions are eligible to apply.

Dr. Linda Stein Gold began serving as one of several judges for Aspire Higher in 2016. She also performs clinical research and cares for patients at the Henry Ford Health System.

**How did you become involved as a judge for the Aspire Higher program?**

I was approached by Ortho Dermatologics, and I thought it was a wonderful opportunity. I really liked that they were giving back to the community and that I could help people who want to further their education.

**What is your favorite part about being a judge for Aspire Higher?**

I really enjoy the whole experience, but two things come to mind: Seeing the impact the scholarships have on the lives of the people who win, and reading their stories.

One of last year's winners left a voicemail for the judges. I was in the middle of grocery shopping when I heard it, and I started crying because it was so touching. Also, reading about how a problem with a person's skin impacts each aspect of their life urges us to seek the best possible treatment for our patients even more. I think that what Ortho Dermatologics is doing is exceptionally worthwhile.

> "It's so satisfying to see how the Aspire Higher scholarship can change somebody's life by helping them further their education."

**What are your thoughts about Ortho Dermatologics' commitment to the dermatology community through this scholarship program?**

I'm thrilled to be part of it. I'm thrilled to have had the opportunity to hear the patients' stories, to understand their journey, and to be part of making their educational dreams come true. I think this is a major gift that Ortho Dermatologics gives back to the community, and it's important to get the word out to our patients that this is available. Ortho Dermatologics really does care about our specialty. ■

ASPIRE HIGHER

Hear from 2017 winner Robby Ruffolo at **aspirehigherscholarships.com**



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# Certification Review

## *All Those Things Inside the Skin You Might Have Forgotten*

*By James A. Van Rhee, MS, PA-C*

*Are you recertifying soon? Start your board review early. Each issue of the JDPA features one board question accompanied by a brief explanation of the answer along with any pertinent test taking tips. Best of luck!*

***QUESTION:*** A sexually active 26-year-old male was diagnosed with pharyngitis 10 days prior to his current presentation and was treated with amoxicillin.He discontinued taking the medication after 5 days since his signs and symptoms resolved. Today he reports severe sore throat and difficulty swallowing. He has a temperature of 102.2° F and his throat examination reveals a swollen soft palate with medial deviation of the uvula. Complete blood count reveals an elevated white blood cell count and increase in neutrophils. Which of the following is the treatment of choice for this patient?

A. Zanamivir
B. Clindamycin
C. Mebendazole
D. Ciprofloxacin
E. Cefotaxime

***EXPLANATION:*** This patient presents with a peritonsillar abscess. Peritonsillar abscess is a complication of adenotonsillitis and is typically due to a combination of aerobic and anaerobic bacterial organisms. Clinically presents with fever, severe odynophagia, extremely swollen or fluctuant tonsil with midline shift of the uvula. Needle aspiration can be both diagnostic and therapeutic. Systemic antibiotics are needed and should cover the predominant organisms such as Streptococcus pyogenes, Staphylococcus aureus (including methicillin-resistant S. aureus), and respiratory anaerobes (such as Fusobacteria and Prevotella). Antibiotics of choice include Amoxicillin-clavulanate or clindamycin; vancomycin can be added is there is a concern about possible infection with MRSA.

*The correct answer is B.*

***James A. Van Rhee, MS, PA-C,*** *is the Program Director for the Yale University School of Medicine Physician Assistant Online Program. Mr. Van Rhee has been involved in physician assistant education for over 20 years. He has served as project director and test item writer for the Physician Assistant Education Association's (PAEA) Physician Assistant Clinical Knowledge Rating Assessment Tool (PACKRAT) and is the author of the Physician Assistant: Certification and Re-certification Review Book, published by Elsevier. For the last fifteen years he has been course director and presenter of the Physician Assistant Board Review, which is now being produced live online by Kaplan Medical.*


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# Erythema Nodosum: A Review and Approach to Evaluation

*By Mallory M. Aycock, MPA, PA-C and Tia M. Solh, MSPAS, PA-C*


## ABSTRACT

Erythema nodosum is a variant of panniculitis most commonly characterized by tender subcutaneous nodules and plaques on the pretibial surface of the bilateral lower extremities. Numerous etiologies have been linked to trigger erythema nodosum, though the pathogenesis of development is poorly understood. A thorough history and physical examination should guide diagnostic testing in patients presenting with erythema nodosum. If identified, treatment should be directed to management of the underlying etiology of erythema nodosum, but supportive measures may be used to improve patient discomfort associated with the classic skin findings.



» CME

*This program has been reviewed and is approved for a maximum of .5 hours of AAPA Category I CME credit by the Physician Assistant Review Panel.*

*Approval is valid for 1 year from the issue date of November 2018. Participants may submit the self-assessment exam at any time during that period.*

*This program was planned in accordance with AAPA's CME Standards for Enduring Material Programs and for Commercial Support of Enduring Material Programs.*

***SDPA members may access the posttest at www.jdpa.org***

### Learning Objectives:

1. *Describe the clinical presentation and diagnostic workup of erythema nodosum.*
2. *Identify etiologies associated with erythema nodosum.*
3. *Review current treatment options for erythema nodosum.*


## INTRODUCTION

Erythema nodosum (EN) is the most common variant of panniculitis.[1-2] It was originally described and categorized in an "erythema" essay in 1798 by Dr. Willan, an English dermatologist.[3] Generations later, EN is now more specifically described as a cutaneous reactive process that can be activated by one of numerous known stimuli.[1-3]

## DEMOGRAPHICS/SPECIAL POPULATIONS

Estimated incidence of EN in the United States is 1 to 5 cases per 100,000 population annually.[4] EN occurs more frequently in females than males (ratio of 5:1) and is usually seen between the second and fourth decades of life.[1,5] In addition, EN occurs in nearly 5% of pregnant women.[5] EN also manifests in patients with systemic illnesses. For example, EN is the most commonly occurring skin manifestation in patients with inflammatory bowel disease, reported in 4 to 15% of patients with Crohn's disease and in 3 to 10% of patients with ulcerative colitis.[5-7] Moreover, twenty-five percent of patients with sarcoidosis develop EN as part of Lofgren syndrome, which occurs in the early stages of sarcoidosis and is associated with a good prognosis.[5]

## PATHOGENESIS AND ETIOLOGY

The pathogenesis of EN is poorly understood. It is currently believed to be a delayed-type hypersensitivity reaction secondary to exposure of various antigens which results in immune complexes depositing in subcutaneous fat.[1,3,8] There has not been one single trigger identified to cause the hypersensitivity reaction, as numerous disease processes have been linked to EN development. There may also be a genetic variability to the development of EN.[1-2]

EN has been documented to be triggered by an extensive number and wide range of disease processes *(Table 1)*.[1-2] Because the spectrum of etiologies is variable, we propose using the following five categories to classify causes of EN: idiopathic, infection, medication, systemic, and malignancy. Utilizing these categories may help providers evaluating patients with EN by focusing

**Table 1**

**Etiologies associated with Erythema Nodosum[1,3,8-12]**

| Idiopathic | |
|---|---|
| **Infections** | **Medications** |
| Ambiasis | Acetaminophen |
| Aspergillosis | Amiodarone |
| Blastomycosis | Antibiotics |
| Borrelia spp. | Azathioprine |
| Brucella spp. | Carbamazepine |
| Campylobacter spp. | Dapsone |
| Cat Scratch Disease | Isotretinoin |
| Chancroid | Methyldopa |
| Chlamydia | NSAIDs |
| Coccidiodomycosis | Omeprazole |
| Corynebacterium diphteriae | Oral contraceptives/Hormonal therapies |
| Cytomegalovirus | Phenytoin |
| Escherichia coli | Thalidomide |
| Giardiasis | Vaccinations |
| Gonorrhea | **Systemic** |
| Hepatitis B virus | Ankylosing spondylitis |
| Hepatitis C virus | Behcet's disease |
| Herpes simplex virus | Berger's disease |
| Histoplasmosis | Celiac disease |
| HIV | Crohn's disease |
| Hookworm infestation | Diverticulitis |
| Epstein-Barr virus | Granulomatosis with polyangiitis |
| Klebsiella spp. | IgA nephropathy |
| Meningococcemia | Pregnancy |
| Moraxella spp. | Polyarteritis nodosa |
| Mycobacteria spp. | Rheumatoid arthritis |
| Mycoplasma spp. | Sarcoidosis |
| Pasteurella spp. | Sjogren's syndrome |
| Pseudomonas spp. | Sweet's syndrome |
| Rickettsia spp. | Systemic lupus erythematosus |
| Salmonella spp. | Takayasu arteritis |
| Shigella spp. | Ulcerative colitis |
| Streptococcus spp. | **Malignancy** |
| Syphilis | Cancers of the colon, kidneys, liver, lung, stomach, pancreas, and uterine cervix |
| Toxoplasma spp. | |
| Trichophyton | Hodgkin's Lymphoma |
| Trichomoniasis | Leukemia |
| Tuberculosis | Lymphoma |
| Tularemia | Sarcoma |
| Upper respiratory tract infections | |
| Yersinia spp. | |
| Varicella | |

**Table 2**

**Differential Diagnoses for Erythema Nodosum[1,3,9]**

| |
|---|
| Cutaneous B-cell lymphoma |
| Cutaneous vasculitides |
| Cytophagic histiocytic panniculitis |
| Erythema induratum of Bazin |
| Lupus panniculitis |
| Necrobiosis lipoidica |
| Necrobiosis xanthogranuloma |
| Nodular vasculitis |
| Polyarteritis nodosa |
| Scleroderma |
| Subcutaneous infections |
| Superficial thrombophlebitis |

the history, examination, and work up necessary to determine underlying etiology or trigger for EN.

It is estimated about half of EN cases are classified as idiopathic, where no underlying condition or trigger is found.[1,9] It is important to note that some literature documents idiopathic EN as "primary EN" and EN cases with underlying causes as "secondary EN."[8,10,11] However, this documentation is not universally agreed upon.

Infectious agents are thought to be the second most common trigger in adult EN cases and the number one trigger in pediatric EN cases.[1,8,9] Streptococcal infections have been reported to be the most common infectious cause of EN.[1,12] Other infections are commonly known to trigger EN, such as upper respiratory infections, HIV, EBV, leprosy (termed erythema nodosum leprosum), tuberculosis, hepatitis, and Yersinia.[1,12-14] Medications should always be considered as a cause of EN.[8] Hormonal therapies, including oral contraceptive pills, along with antibiotics and vaccinations are known to be common triggers of EN.[1,12]

Systemic causes comprise a large group of diseases associated with EN. The most common systemic processes that trigger EN are pregnancy and sarcoidosis.[1,2,12,14,15] Other well documented systemic causes include Behcet's syndrome, Sjogren's syndrome, reactive arthritis, inflammatory bowel disease, Sweet's syndrome, and systemic lupus erythematosus.[1,8,10,12,14]

Malignancy is a rare cause of EN.[1,9] Hodgkin's lymphoma and hematologic malignancies should be considered in the differential diagnosis when evaluating a patient with EN.[1,11,12] Other rare malignancies that may present with EN include pancreatic and colorectal cancers.[9] EN may be present as a presenting symptoms of malignancy or indicate recurrence of disease.[9]

## PATIENT PRESENTATION

Because of the spectrum of diseases associated with EN, it is important to perform a thorough history and physical examination. Multiple associated historical and examination findings may be present based on underlying conditions that have triggered EN. Skin findings may be preceded by symptoms of a nonspecific, systemic illness, including fatigue, fever, malaise, arthralgias, abdominal pain, and cough.[1,16,17] These constitutional symptoms may herald EN nodule formation by 1 to 3 weeks. A prospective study (Psychos et al) of 132 patients with confirmed EN noted fever (50% of patients), arthralgias (38%), fatigue or weakness (30%), sore throat (19%), dry cough (17%), and myalgias (15%) were the most commonly reported presenting symptoms.[14] Physical examination confirmed fever (50%), arthritis (11%), and pharyngitis (17%) in these patients. In addition, in a study of 50 patients with confirmed EN, Mert et al reported that fever (58% of patients), arthralgias (44%), fatigue (32%), cough (26%), and weight loss (16%) were the most common presenting constitutional symptoms.[10]

On physical exam, EN typically presents as symmetrical tender and warm subcutaneous nodules and plaques on the pretibial surface of the lower extremities.[1,2,18] Lesions are classically 1-5cm in size and may coalesce as EN advances.[1-3] There is absence of ulceration or atrophy associated with the lesions.[1,8,11] Resolved EN lesions heal without scarring, and may progressively heal from a nodular or plaque-like state to ecchymosis before complete resolution; lesions may be observable in variable stages of healing.[1,2,11] Evolution to a "bruise-like" appearance, also known as "erythema contusiformis," in the healing process is a hallmark sign of EN and may be helpful in making the diagnosis of EN.[1,3,8] The lesions are characteristically erythematous, but may appear violaceous or hyperpigmented in the acute stages with a yellow-green to brown coloration in the healing phases of erythema contusiformis.[2,3,8,11]

The most common sites for EN are the shins, however any site on the body can be involved, including the face, knees, thighs, forearms, trunk, and buttocks.[1,3,9,18] The most common additional finding seen on examination is a low-grade fever (about 100.4-102.2°F).[1,3,8] However, additional physical findings are frequent and variable based on underlying trigger. For this reason, other findings, such as hepatosplenomegaly, lymphadenopathy, pharyngitis, joint edema, conjunctivitis, and oral ulcers, may be present.[3,8,10,14] A thorough complete physical examination should be performed alongside a complete skin examination with or without consultation with a primary care provider.

## DIAGNOSTIC WORKUP

Because of the large number of etiologies associated with EN, an initial diagnostic workup may be challenging. Approach to evaluation should be cost-effective and guided by patient specific historical and physical findings. Initial testing should include complete blood count with differential, erythrocyte sedimentation rate, urinalysis, and tuberculin testing.[8,9,11] Additionally, at least two serial antistreptolysin O titers should be performed at 2 week intervals.[8,9,11]

Ideally, a thorough history and physical examination will direct secondary studies necessary to rule out underlying conditions in patients with EN. These tests may include chest radiography, angiotensin converting enzyme levels, rheumatoid factor, antinuclear antibody, throat culture, and C-reactive protein levels.[8-9] In patients with gastrointestinal complaints, consideration for stool culture, stool ova and parasite evaluation, and assessment for inflammatory bowel disease may be warranted.[1,8-9] Specific testing for suspected infectious causes may be considered, especially for infectious agents endemic to patient's region of origin or recent travel destinations.[1,3]

A biopsy can be performed to confirm the diagnosis of EN, especially in cases with atypical presentations.[1-2,9] Because EN is a form of panniculitis, special care should be taken to obtain adequate samples of subcutaneous tissue. Techniques to ensure adequate sampling include excisional biopsy, punch biopsy, double punch biopsy, or novel punch biopsy techniques described by Ersoy-Evans.[19]

## TREATMENT

***First-line therapy*** - The current treatment approach to EN is based on a number of case reports and case series, as no published randomized trials currently exist.[1] If known, the treatment of EN should be directed at the underlying cause.[5,16,20] Therefore, if EN manifests in association with a systemic disease such as inflammatory bowel disease, infectious process such as streptococcal pharyngitis, or malignancy such as a paraneoplastic syndrome, the underlying condition should be treated first.[5,6,16,20] Supportive measures may be added to reduce associated patient discomfort; these include rest, elevation of the effected extremities, and compression stockings.[1,16,20] Moreover, symptomatic treatment may be all that is required for mild cases of idiopathic EN.[1,20] If further measures are necessary to address associated discomfort, nonsteroidal anti-inflammatory drugs such as naproxen 250mg twice daily as needed, and indomethacin 50mg every 8 to 12 hours as

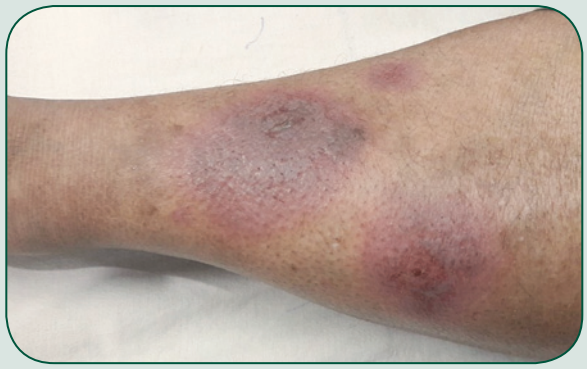

**Photo 1:** Erythema nodosum (EN) associated with systemic lupus erythematosus (SLE).
*https://commons.wikimedia.org/wiki/File:Erythema_Nodosum.jpg*

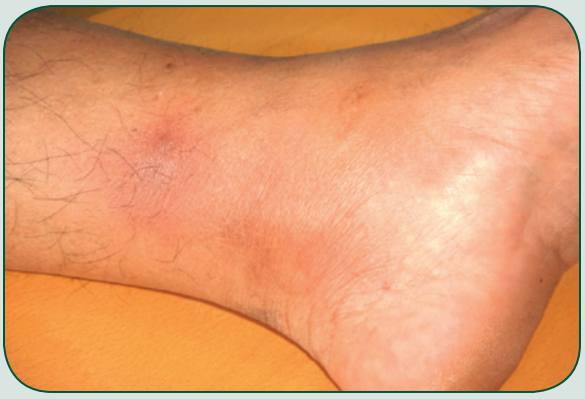

**Photo 2:** Erythema nodosum (EN)
*https://commons.wikimedia.org/wiki/File:EN-TBC.PNG*

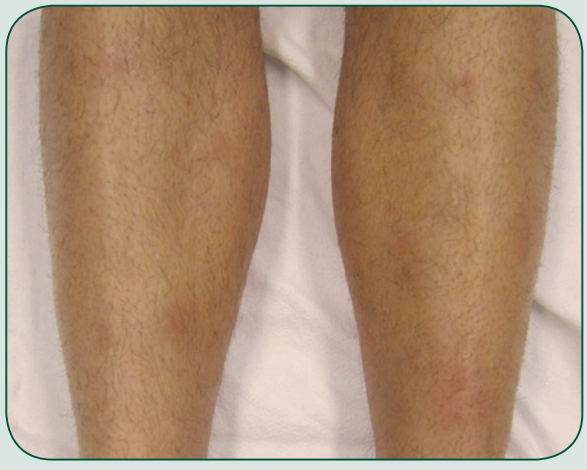

**Photo 3:** Erythema nodosum (EN)
*https://commons.wikimedia.org/wiki/File:Erythema_nodosum_on_hairy_legs.jpg*

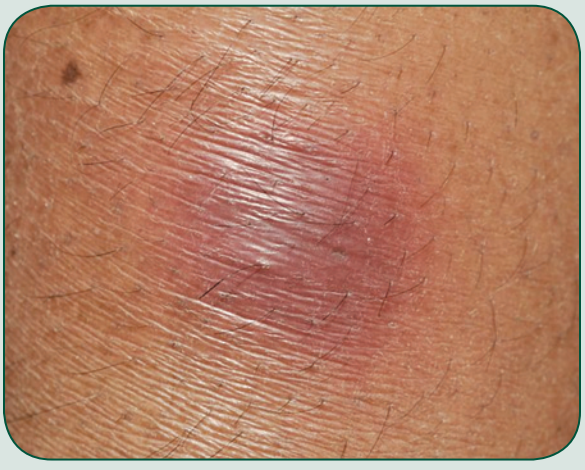

**Photo 4;** Erythema nodosum (EN)
*https://commons.wikimedia.org/wiki/File:Erythema_nodosum_-_Kolkata_2012-01-03_7753.JPG*

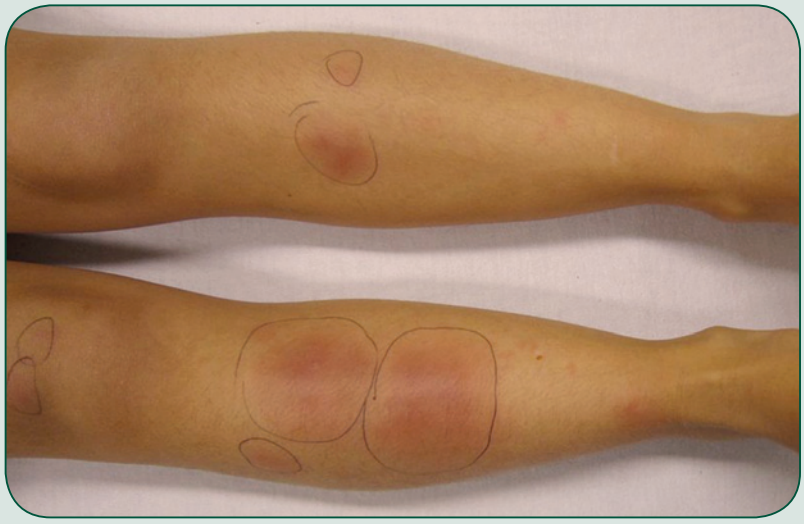

**Photo 5:** Erythema nodosum (EN)
*https://commons.wikimedia.org/wiki/File:ENlegs.JPG*

needed, are considered first-line.[1,16,20] However, NSAIDs should be avoided in patients with EN secondary to inflammatory bowel disease, as they may elicit an acute exacerbation.[16] In cases of prolonged or moderate to severe EN, potassium iodide can be given at a dose of 300mg three times a day.[20-21] Potassium iodide has been shown in several small studies to resolve nodules within 2 weeks and improve symptoms within 1 to 2 days.[21]

***Second-line therapy*** - While systemic corticosteroids are rarely needed, a short course may be considered after first-line therapies have been exhausted, or in severe cases of associated inflammatory bowel disease, as they have been reported to improve lesions as well as the underlying disease process.[22] However, the possibility of underlying infection as well as malignancy must be ruled out prior to administration.[7,16,20] Prednisone at a dosage of 40mg per day has been reported to resolve nodules quickly.[20]

Intralesional corticosteroid injections may also incite swift resolution of refractory nodules.[20] Triamcinolone acetonide 5mg/ml injected into the center of the lesion, has been reported to be successful.[16,20] Dapsone, colchicine, and hydroxychloroquine have all been used to treat refractory, chronic or recurring EN, though the data to support the efficacy of these agents is limited to case reports or case series.[1,16,20] In addition, tumor necrosis factor (TNF)-alpha inhibitors, such as infliximab and adalimumab, have been reported to be beneficial in severe cases of associated inflammatory bowel disease.[1,7,16]

## TREATMENT IN PREGNANCY

The current recommended first-line pharmacologic treatment options for EN are generally avoided in pregnancy. For example, potassium iodide should be avoided in pregnancy because of the risk of goiter and hypothyroidism in the fetus.[20,23] Likewise, because of possible teratogenic effects, NSAIDs are not recommended during the first or third trimester of pregnancy, due to the risk of cardiac defects and closure of the ductus arteriosus, respectively.[23] Therefore, treatment in pregnancy should be limited to symptomatic, supportive treatment whenever possible, such as bed rest and elastic web bandages.[23] If supportive measures are insufficient, available pharmacologic treatment options must be carefully considered on an individual basis, in consultation with the patient's obstetrician.[23]

## PROGNOSIS

EN is typically self-limited, and usually resolves spontaneously within 3 to 4 weeks of onset, though severe cases may last up to 6 weeks.[1,16,20] Relapses have been estimated to occur in up to one third of patients, and may occur months to years after the initial onset.[24] Relapses are also thought to more commonly occur in patients with idiopathic EN or in association with streptococcal infection, but complications are rare.[20]

## CONCLUSION

Though EN is a poorly understood form of panniculitis, more etiologies have been identified and linked to this disease process. Understanding categories of triggers can help providers improve patient evaluation and care. Though EN is often self-limited, awareness of management options for patients with EN is crucial. Patients with this unique disorder should always be assessed individually to determine the most appropriate steps for evaluation and management.

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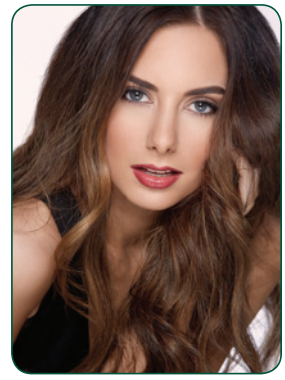
# From The Patient's Perspective

# Early Detection Essential for Nail Melanoma

## *Miss Illinois USA 2018 Shares Her Story*

Karolina Jasko's nails were usually painted during her senior year of high school, so she didn't notice the black vertical line on her right thumbnail until a nail technician pointed it out - and at the time, she didn't think much of it.



*Karolina Jasko*

When that same nail started to show signs of infection, however, she decided to seek medical attention, and she was shocked to be diagnosed with nail melanoma. "My mom was freaking out even more than I was, I think, because she had melanoma before, so she knew what it was like," says Jasko, now a University of Illinois at Chicago student who is currently reigning as Miss Illinois USA 2018.

Three surgeries later, Jasko's thumbnail is gone, but so is her melanoma. "I'm a little self-conscious about it, but I was lucky," she says. "The doctors originally thought they would have to remove my whole thumb, and you never realize how much you use your right thumb until you think about losing it. And if I had waited any longer to see a doctor and have my first surgery, the melanoma could have spread through my whole body, and it would have been a lot worse."

As Jasko's story shows, early detection of nail melanoma is important, says board-certified dermatologist and nail specialist Shari Lipner, MD, PhD, FAAD. Because the disease is commonly overlooked and diagnosed late, she says, it often has a poor prognosis, which could result in the amputation of the affected finger or even death. "It's important to regularly examine your whole body for signs of melanoma and other skin cancers, and that includes your nails," she says.

*Shari Lipner, MD, PhD, FAAD*

According to Dr. Lipner, ultraviolet radiation exposure is likely not an important risk factor for nail melanoma, as it is for melanoma of the skin. Instead, she says, the two main risk factors for nail melanoma are previous nail trauma and a personal or family history of melanoma. Although anyone can develop nail melanoma, she says, the incidence is higher in older individuals and people with skin of color.

The main sign of nail melanoma is a brown or black band in the nail, often on the thumb or big toe of one's dominant hand, Dr. Lipner says. However, there are many other potential causes of such dark bands, most

of which are benign, she says, including blood under the nail as the result of injury or overly tight shoes, a bacterial or fungal infection, or residual pigment from substances like silver nitrate or newspaper print.

Additional warning signs that distinguish nail melanoma from other causes of dark nail bands include the presence of pigment on the adjacent skin, splitting or bleeding of the nail, or infection-like symptoms such as drainage, pus and pain, Dr. Lipner says. As with other types of melanoma, she says, any change to the nail is also an important warning sign.

"Because early detection plays such a big role in nail melanoma prognosis, it's important to keep an eye on your nails and be aware of any changes to them," Dr. Lipner says. "If you notice a new dark band on your nail, or any band that is getting wider or darker, you should see a board-certified dermatologist as soon as possible."

Jasko agrees. "People may not realize that you can get melanoma in your nails, but it's important to be aware of that risk," she says. "If you have the slightest concern about something on your nail, go and get it checked out by a dermatologist; it could end up saving your finger, or your life."

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## Journal Club: *Practice Changing Articles for Dermatology PAs*

# Merkel cell carcinoma: Current US Incidence and Projected Increases Based on Changing Demographics

J Am Acad Dermatol. 2018 Mar; 78(3):457-463

Paulson KG1,[2], Park SY[2], Vandeven NA[2], Lachance K[2], Thomas H[2], Chapuis AG[1,2], Harms KL[3], Thompson JA[1,2], Bhatia S[1,2], Stang A[4], Nghiem P[1,2]

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## Background

Merkel cell carcinoma (MCC) incidence rates are rising and strongly age-associated, relevant for an aging population.

## Objective

Determine MCC incidence in the United States and project incident cases through the year 2025.

## Methods

Registry data were obtained from the SEER-18 Database, containing 6600 MCC cases. Age-and sex-adjusted projections were generated using US census data.

## Results

During 2000-2013, the number of reported solid cancer cases increased 15%, melanoma cases increased 57%, and MCC cases increased 95%. In 2013, the MCC incidence rate was 0.7 cases/100,000 person-years in the United States, corresponding to 2488 cases/year. MCC incidence increased exponentially with age, from 0.1 to 1.0 to 9.8 (per 100,000 person-years) among age groups 40-44 years, 60-64 years, and ≥85 years, respectively. Due to aging of the Baby Boomer generation, US MCC incident cases are predicted to climb to 2835 cases/year in 2020 and 3284 cases/year in 2025.

## Limitations

We assumed that the age-adjusted incidence rate would stabilize, and thus, the number of incident cases we projected might be an underestimate.

## Conclusion

In aging population is driving brisk increases in the number of new MCC cases in the United States. This growing impact combined with the rapidly evolving therapeutic landscape warrants expanded awareness of MCC diagnosis and management.

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*Journal clubs are a great way to review and critically evaluate the most current literature impacting the practice of dermatology. For PAs who are new to the practice of dermatology, journal clubs can assist them to become more familiar with advanced medical literature and improve their understanding of current issues within the field. The articles selected for the JDPA Journal Club are meant to be shared and discussed with your colleagues, peers, and collaborating physicians. If you have any articles to recommend for the JDPA Journal Club, please email them to editor@jdpa.org.*


# The Only FDA Approved Clobetasol Propionate 0.025%

**IMPOYZ™ (clobetasol propionate) Cream 0.025% is indicated for the treatment of moderate to severe plaque psoriasis in patients 18 years of age and older.[1]**

impoyz™
(clobetasol propionate)
Cream, 0.025%

**IMPORTANT SAFETY INFORMATION**

**Warnings and Precautions**

Topical corticosteroids, including IMPOYZ Cream can cause reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency. This may occur during treatment or after withdrawal of treatment. This may require that patients be evaluated periodically for evidence of HPA axis suppression. Factors that predispose to HPA axis suppression include, use of high-potency steroids, large treatment surface areas, prolonged use, use of occlusive dressings, altered skin barrier, liver failure, and young age. If HPA axis suppression occurs, gradually withdraw the drug, reduce frequency of application, or substitute with a less potent corticosteroid. If signs and symptoms of withdrawal occur, systemic corticosteroids may be required. Recovery of HPA axis function is generally prompt and complete upon discontinuation of topical corticosteroids. Although rare, systemic effects of topical corticosteroids may manifest as Cushing's syndrome, hyperglycemia, and glucosuria. Pediatric patients may be more susceptible to systemic toxicity because of their larger skin surface to body mass ratios. **Local Adverse Reactions with Topical Corticosteroids -** Local adverse reactions from topical corticosteroids may be more likely to occur with occlusion, prolonged use, or use of higher potency corticosteroids. Some local adverse reactions may be irreversible. **Concomitant Skin Infections -** Use an appropriate antimicrobial agent if a skin infection is present or develops. If appropriate, discontinue use of IMPOYZ Cream. **Allergic Contact Dermatitis -** Allergic contact dermatitis with corticosteroids is usually diagnosed by observing failure to heal rather than noting a clinical exacerbation. **Adverse Events -** The adverse reaction that occurred in at least 1% of subjects treated with IMPOYZ Cream and at a higher incidence than in subjects treated with vehicle cream was application site discoloration (2% versus 1%). Less common local adverse events occurring in < 1% of subjects treated with IMPOYZ Cream were application site atrophy, telangiectasia and rash.

1. Impoyz Cream full Prescribing Information.

**Please see Brief Summary of Full Prescribing Information on the following pages.**

CLB1214 4/18

**This Brief Summary does not include all the information needed to use IMPOYZ safely and correctly. See full Prescribing Information.**
**IMPOYZ (clobetasol propionate) Cream, 0.025%, for topical use**

**INDICATIONS AND USAGE**

IMPOYZ Cream 0.025% is indicated for the treatment of moderate to severe plaque psoriasis in patients 18 years of age and older.

**DOSAGE AND ADMINISTRATION**

Apply a thin layer of IMPOYZ Cream to the affected skin areas twice daily and rub in gently and completely. Use IMPOYZ Cream for up to 2 consecutive weeks of treatment. Treatment beyond 2 consecutive weeks is not recommended, and the total dosage should not exceed 50 g per week because of the potential for the drug to suppress the hypothalamic-pituitary-adrenal (HPA) axis [see Warnings and Precautions (5.1)]. Discontinue IMPOYZ Cream when control is achieved. Do not use if atrophy is present at the treatment site. Do not bandage, cover, or wrap the treated skin area unless directed by a physician. Avoid use on the face, scalp, axilla, groin, or other intertriginous areas. IMPOYZ Cream is for topical use only. It is not for oral, ophthalmic, or intravaginal use. Wash hands after each application.

**DOSAGE FORMS AND STRENGTHS**

Cream, 0.025%: each gram contains 0.25 mg of clobetasol propionate in a white to off-white cream base.

**CONTRAINDICATIONS**. None

**WARNINGS AND PRECAUTIONS**

**Effects on the Endocrine System:** IMPOYZ Cream can cause reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency. This may occur during treatment or after withdrawal of treatment. Because of the potential for systemic absorption, use of topical corticosteroids, including IMPOYZ Cream, may require that patients be evaluated periodically for evidence of HPA axis suppression. Factors that predispose a patient to HPA axis suppression include the use of high-potency steroids, large treatment surface areas, prolonged use, use of occlusive dressings, altered skin barrier, liver failure, and young age. Evaluation for HPA axis suppression may be done by using the adrenocorticotropic hormone (ACTH) stimulation test. In a trial evaluating the effects of IMPOYZ Cream on the HPA axis, subjects with plaque psoriasis applied IMPOYZ Cream twice daily to at least 20% of involved Body Surface Area (BSA) for 15 days. Abnormal ACTH stimulation tests suggestive of HPA axis suppression were seen in 3 of 24 (12.5%) subjects on IMPOYZ Cream [see Clinical Pharmacology (12.2)]. In another trial to evaluate the effects of IMPOYZ Cream on the HPA axis, subjects with moderate to severe plaque psoriasis applied IMPOYZ Cream twice daily to at least 25% of involved BSA for 28 consecutive days. Abnormal ACTH stimulation test suggestive of HPA axis suppression was seen in 8 of 26 (30.8%) of subjects on IMPOYZ Cream. If HPA axis suppression is documented, gradually withdraw the drug, reduce the frequency of application, or substitute with a less potent corticosteroid. If signs and symptoms of steroid withdrawal occur, supplemental systemic corticosteroids may be required. Recovery of HPA axis function is generally prompt and complete upon discontinuation of topical corticosteroids. Systemic effects of topical corticosteroids may also manifest as Cushing's syndrome, hyperglycemia, and glucosuria. These complications are rare and generally occur after prolonged exposure to larger than recommended doses, particularly with high-potency topical corticosteroids. Use of more than one corticosteroid-containing product at the same time may increase the total systemic exposure to topical corticosteroids. Minimize the unwanted risks from endocrine effects by mitigating risk factors favoring increased systemic bioavailability and by using the product as recommended [see Dosage and Administration (2)]. Pediatric patients may be more susceptible to systemic toxicity because of their larger skin surface to body mass ratios [see Use in Specific Populations (8.4)].

**Local Adverse Reactions with Topical Corticosteroids**

Local adverse reactions from topical corticosteroids may include atrophy, striae, telangiectasias, burning, itching, irritation, dryness, folliculitis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, and miliaria. These may be more likely to occur with occlusive use, prolonged use, or use of higher potency corticosteroids, including IMPOYZ Cream. Some local adverse reactions may be irreversible.

**Concomitant Skin Infections:** Use an appropriate antimicrobial agent if a skin infection is present or develops. If a favorable response does not occur promptly, discontinue use of IMPOYZ Cream until the infection has been adequately treated.

**Allergic Contact Dermatitis:** Allergic contact dermatitis with corticosteroids is usually diagnosed by observing failure to heal rather than noting a clinical exacerbation. Such an observation should be corroborated with appropriate diagnostic patch testing. If irritation develops, discontinue the topical corticosteroid and institute appropriate therapy.

**ADVERSE REACTIONS**

**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. IMPOYZ Cream was evaluated in two randomized, multicenter, prospective, vehicle-controlled clinical trials in subjects with moderate to severe plaque psoriasis. Subjects applied IMPOYZ Cream or vehicle cream twice daily for 14 days. A total of 354 subjects applied IMPOYZ Cream and 178 subjects applied vehicle. The adverse reaction that occurred in at least 1% of subjects treated with IMPOYZ Cream and at a higher incidence than in subjects treated with vehicle cream was application site discoloration (2% versus 1%). Less common local adverse events occurring in < 1% of subjects treated with IMPOYZ Cream were application site atrophy, telangiectasia and rash.

**Postmarketing Experience**

The following adverse reactions have been identified during post-approval use of clobetasol propionate: striae, irritation, dryness, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, hypertrichosis, and miliaria. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

**USE IN SPECIFIC POPULATIONS**

**Pregnancy**: Risk Summary There are no available data on IMPOYZ Cream in pregnant women to inform a drug-associated risk for adverse developmental outcomes. Published data report a significantly increased risk of low birthweight with the use of greater than 300 grams of potent or very potent topical corticosteroid during a pregnancy. Advise pregnant women of the potential risk to a fetus and to use IMPOYZ Cream on the smallest area of skin and for the shortest duration possible (see Data). In animal reproduction studies, increased malformations, such as cleft palate and skeletal abnormalities, were observed after subcutaneous administration of clobetasol propionate to pregnant mice and rabbits. No comparisons of animal exposure with human exposure are provided due to minimal systemic exposure noted after topical administration of IMPOYZ Cream [see Clinical Pharmacology (12.3)]. The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Data

*Human Data*

Multiple observational studies found no significant associations between maternal use of topical corticosteroids of any potency and congenital malformations, preterm delivery, or fetal mortality. However, when the dispensed amount of potent or very potent topical corticosteroid exceeded 300 g during the entire pregnancy, use was associated with an increase in low birth weight infants [adjusted RR, 7.74 (95% CI, 1.49–40.11)]. In addition, a small cohort study, in which 28 sub-Saharan women using potent topical corticosteroids (27/28 used clobetasol propionate 0.05%) for skin lightening during pregnancy, noted a higher incidence of low birth weight infants in the exposed group. The majority of exposed subjects treated large areas of the body (a mean quantity of 60 g/month (range, 12–170g) over long periods of time.

*Animal Data*

In an embryo fetal development study in mice, subcutaneous administration of clobetasol propionate resulted in fetotoxicity at the highest dose tested (1 mg/kg) and malformations at the lowest dose tested (0.03 mg/kg). Malformations seen included cleft palate and skeletal abnormalities. In an embryofetal development study in rabbits, subcutaneous administration of clobetasol propionate resulted in malformations at doses of 0.003 and 0.01 mg/kg. Malformations seen included cleft palate, cranioschisis, and other skeletal abnormalities.

**Lactation:** Risk Summary There is no information regarding the presence of clobetasol propionate in breast milk or its effects on the breastfed infant or on milk production. Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not known whether topical administration of clobetasol propionate could result in sufficient systemic absorption to produce detectable quantities in human milk. The developmental and health benefits of breast-feeding should be considered along with the mother's clinical need for IMPOYZ Cream and any potential adverse effects on the breastfed infant from IMPOYZ Cream or from the underlying maternal condition. Clinical Considerations: To minimize potential exposure to the breastfed infant via breast milk, use IMPOYZ Cream on the smallest area of skin and for the shortest duration possible while breastfeeding. Advise breastfeeding women not to apply IMPOYZ Cream directly to the nipple and areola to avoid direct infant exposure.
**Pediatric Use:** The safety and effectiveness of IMPOYZ Cream in patients younger than 18 years of age have not been established; therefore, use in children younger than 18 years is not recommended. Because of a higher ratio of skin surface area to body mass, pediatric patients are at a greater risk than adults of systemic toxicity, including HPA axis suppression, when treated with topical drugs [see Warnings and Precautions (5.1)]. Rare systemic toxicities such as Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in pediatric patients, especially those with prolonged exposure to large doses of high potency topical corticosteroids. Local adverse reactions including striae and skin atrophy have also been reported with use of topical corticosteroids in pediatric patients. Avoid use of IMPOYZ Cream in the treatment of diaper dermatitis.
**Geriatric Use:** Clinical studies of IMPOYZ Cream did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience with topical corticosteroids has not identified differences in responses between the elderly and younger patients.
**NONCLINICAL TOXICOLOGY Carcinogenesis, Mutagenesis, Impairment of Fertility:** Long-term animal studies have not been performed to evaluate the carcinogenic potential of clobetasol propionate cream. In a 13-week repeat dose toxicity study in rats, topical administration of clobetasol propionate cream, 0.001, 0.005 and 0.025 % at corresponding doses of 0.004, 0.02 and 0.1 mg/kg/day resulted in corticosteroid class-related systemic effects such as reductions in body weight gain, reductions in total leukocytes and individual white cells, decrease in weight of adrenals, thymus, spleen, liver and lung. Histologically, there were decreased hematopoiesis in the bone marrow, thymic atrophy and mast cell infiltration of the mesenteric lymph nodes. All these effects were indicative of severe immune suppression consistent with long-term exposure to corticosteroids. A no observable adverse effect level (NOAEL) was determined to be clobetasol propionate cream, 0.001% (0.004 mg/kg/day) in male rats while a NOAEL could not be determined in females. The clinical relevance of the findings in animals to humans is not clear, but sustained glucocorticoid-related immune suppression may increase the risk of infection and possibly the risk of carcinogenesis. Clobetasol propionate was not mutagenic in three different test systems: the Ames test, the Saccharomyces cerevisiae gene conversion assay, and the E. coli B WP2 fluctuation test. Fertility studies conducted in the rat following subcutaneous administration of clobetasol propionate at dosage levels up to 0.05 mg/kg/day revealed that females exhibited an increase in the number of resorbed embryos and a decrease in the number of living fetuses at the highest dose.

Manufactured by DPT Laboratories Ltd., San Antonio, TX 78215 For Encore Dermatology, Inc., Scottsdale, AZ 85254

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CLB1214 4/18

SURGICAL wisdom

# Dermcast.tv Blog -

## *Soothing Surgery Jitters…Could A Stress ball or Hand-Holding Help?*

*By Martha L. Sikes, MS, RPh, PA-C*

Many skin cancer surgeries are performed using a local anesthetic. While this is preferable to full sedation, there may be more patient anxiety associated with being alert and awake during procedures. In other surgical fields, there is some indication that hand-holding and other relaxation methods help patients feel more at ease.

A recent study looked at whether hand-holding or holding a stress ball reduced patient anxiety during a nonmelanoma skin cancer excision. Patients were randomized into three groups: hand-holding, stress ball use, or control (treatment as usual). Anxiety level was measured for all groups both before and right after the procedure began using a visual analog scale (VAS), the 6-item State Trait Anxiety Inventory (STAI), and physiologic measures such as blood pressure and heart rate.

The results showed that for all patients' anxiety was reduced immediately after the procedure began, but there was no significant difference between the three groups. Anecdotally, some patients in the hand-holding or stress ball groups did report feeling less anxiety, but the data did not support significant differences in the interventions. There were also no significant differences in how the patients ranked their post procedure pain levels or patient satisfaction. Patients were also asked how many hours they spent researching their procedure beforehand; those that had researched had significantly increased levels of anxiety before the procedure.

The authors conclude that although the study did not show a cohort-wide effect, some subgroups may still benefit from these low cost interventions. In addition, patients may appreciate reassuring preoperative informational materials before procedures to help counter any anxiety-producing information they may find during their own research.

Dermcast.tv Blog Post: August 23, 2018
Source: JAMA
*Adapted from the original article.*

*Dermcast.tv is the official online media resource of the SDPA and is your free source for the latest SDPA-related audio podcasts, current dermatology news and research, and videos featuring thought-leaders, procedures, conference highlights, and much more. In addition, Dermcast is the #1 dermatology-related podcast on iTunes! To read more Dermcast.tv Blogs and/or to follow the next live blog from an upcoming SDPA dermatology conference, please visit the Dermcast.tv website at www.dermcast.tv and subscribe today.*

## Journal Club: *Practice Changing Articles for Dermatology PAs*

# Use of Medical Photography Among Dermatologists: a Nationwide Online Survey Study

J Eur Acad Dermatol Venereol. 2018 Oct; 32(10):1804-1809

Milam EC[1], Leger MC[2]

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## Background

Medical photography enhances patient care, medical education and research. Despite medical photography's widespread use, little is known about how dermatologists choose to implement photography in routine clinical practice, and how they approach issues of image storage, image security and patient consent.

## Objective

To characterize dermatologists' medical photography habits and opinions.

## Methods

A 32-item anonymous, multiple-choice SurveyMonkey questionnaire about medical photography practices was emailed to programme directors of the 117 United States (US) dermatology residency programmes between May and August 2015, with a request to forward to faculty and affiliated dermatologists. Only board-certified dermatologists practicing in the United States were eligible. The Institutional Review Board exempted our study from full review.

## Results

Our survey included 153 board-certified dermatologists, primarily representing the north-east (43.1%) and identifying as academic dermatologists (75.5%). Medical photography is prevalent: 61.8% report everyday use and 21.7% photograph every patient. Those reporting rare use (3.3%) were, on average, 20 years older. Dermatologists most commonly use photography to mark biopsy sites (87.5%), track disease (82.9%) and for education/teaching (72.4%). Nearly half (46%) use smartphone cameras. Emailing and texting photographs with patients or colleagues are common (69.1%). Most dermatologists (75.7%) always request patient consent for photographs. Only 23.7% adhere to a photography protocol and 73.9% desire more training opportunities.

## Conclusion

Dermatologists value medical photography. While patterns of image acquisition, storage and consent are noted, a variety of methods and preferences exist. Clearer photography guidelines and increased educational resources are likely to improve image quality, exchangeability and confidentiality.

From MEDLINE®/PubMed®, a database of the U.S. National Library of Medicine. PreMedline Identifier: 29405432.

*Journal clubs are a great way to review and critically evaluate the most current literature impacting the practice of dermatology. For physician assistants who are new to the practice of dermatology, journal clubs can assist them to become more familiar with advanced medical literature and improve their understanding of current issues within the field. The articles selected for the JDPA Journal Club are meant to be shared and discussed with your colleagues, peers, and supervising physicians. If you have any articles to recommend for the JDPA Journal Club, please email them to editor@jdpa.org.*

# COSMETIC pearls

## Dermcast.tv Blog

## *Are Chemical Peels Safe For Darker Skin?*

*By Martha L. Sikes, MS, RPh, PA-C*

Chemical peels are effective and common treatments for many skin problems such as photoaging, lentigines, melisma, and other pigmentary changes. Different chemical peels act on different depths of the skin layers. Alpha-hydroxy acids such as glycolic acid (GA) 20%-50%, lactic acid (LA) 20%-30%, and mandelic acid (MA) are classified as superficial peeling agents and act on the epidermis, preserving the basal layer. These are all considered safe for all skin types, but MA is considered the safest choice. Salicylic acid (SA) is a beta-hydroxy acid and has been considered to be the safest peel in skin of color.

All of the peeling agents have some side effects, most commonly swelling, crusting, and post-inflammatory hyperpigmentation (PIH). Previous studies have suggested that the deeper the peel and the darker the skin tone, the more side effects and complications can be expected, especially PIH. However, the data on how different skin tones fare with different peels is limited, so a recent study examined the frequency and range of side effects associated with superficial chemical peels in ethnically diverse patients.

The retrospective study included 132 patients with skin types III-VI who received a total of 473 chemical peels over a five-year period at a Boston medical center by a single dermatologist. Patients received the peels to treat melasma, PIH, acne, acanthosis, lentigines, and photoaging. The study catalogued side effects that included the development of dyspigmentation, erythema, crusting, or blisters and noted whether they lasted more or less than two weeks.

The results showed that in this population, only a small percentage of treatments (3.8%) resulted in either short or long-term (over 2 weeks) side effects. This is lower than in previous studies on darker skin. The most common effects were prolonged crust (2.3%), PIH (1.9%), and erythema (1.9%) and complications were less frequent when the treatment was done in winter and were more common in skin type VI - average duration was 4.5 weeks.

The authors conclude that based on the data superficial chemical peels are safe in darker skin types and result in few side effects and complications.

Dermcast.tv Blog Post: Septemeber 20, 2018
Source: JAAD
*Adapted from the original article*

*Dermcast.tv is the official online media resource of the SDPA and is your free source for the latest SDPA-related audio podcasts, current dermatology news and research, and videos featuring thought-leaders, procedures, conference highlights, and much more. In addition, Dermcast is the #1 dermatology-related podcast on iTunes! To read more Dermcast.tv Blogs and/or to follow the next live blog from an upcoming SDPA dermatology conference, please visit the Dermcast.tv website at www.dermcast.tv and subscribe today.*

# ILUMYA™
tildrakizumab-asmn

# NOW APPROVED

## FOR MODERATE-TO-SEVERE PLAQUE PSORIASIS

**ILUMYA™** (tildrakizumab-asmn) is an interleukin-23 antagonist indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

A NEW IL-23 INHIBITOR[1]

## IMPORTANT SAFETY INFORMATION

### CONTRAINDICATIONS

ILUMYA is contraindicated in patients with a previous serious hypersensitivity reaction to tildrakizumab or to any of the excipients.

### WARNINGS AND PRECAUTIONS

**Hypersensitivity**

Cases of angioedema and urticaria occurred in ILUMYA-treated subjects in clinical trials. If a serious allergic reaction occurs, discontinue ILUMYA immediately and initiate appropriate therapy.

**Infections**

ILUMYA may increase the risk of infection. Treatment with ILUMYA should not be initiated in patients with a clinically important active infection until the infection resolves or is adequately treated.

Consider the risks and benefits of treatment prior to prescribing ILUMYA in patients with a chronic infection or a history of recurrent infection. Instruct patients receiving ILUMYA to seek medical help if signs or symptoms of clinically important chronic or acute infection occur. If a patient develops a clinically important or serious infection, or is not responding to standard therapy, closely monitor and consider discontinuation of ILUMYA until the infection resolves.

**Pretreatment Evaluation for Tuberculosis**

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

**Immunizations**

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

**Adverse Reactions**

The most common (≥1%) adverse reactions associated with ILUMYA treatment that were more frequent than in the placebo group are upper respiratory infections, injection-site reactions, and diarrhea.

**Please see brief summary of Full Prescribing Information on next page or visit ILUMYApro.com for Full Prescribing Information.**

Reference: 1. ILUMYA™ [package insert]. Princeton, NJ: Sun Pharmaceuticals, Inc.

SUN DERMATOLOGY



ILUMYAPRO.COM

**Brief Summary of Prescribing Information for ILUMYA™ (tildrakizumab-asmn)**
**ILUMYA™ (tildrakizumab-asmn) injection, for subcutaneous use**
**See package insert for full Prescribing Information**

**INDICATIONS AND USAGE** ILUMYA™ is indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

**CONTRAINDICATIONS**
ILUMYA is contraindicated in patients with a previous serious hypersensitivity reaction to tildrakizumab or to any of the excipients *[see Warnings and Precautions]*.

**WARNINGS AND PRECAUTIONS**
**Hypersensitivity:** Cases of angioedema and urticaria occurred in ILUMYA treated subjects in clinical trials. If a serious hypersensitivity reaction occurs, discontinue ILUMYA immediately and initiate appropriate therapy *[see Adverse Reactions]*.

**Infections:** ILUMYA may increase the risk of infection. Although infections were slightly more common in the ILUMYA group (23%), the difference in frequency of infections between the ILUMYA group and the placebo group was less than 1% during the placebo-controlled period. However, subjects with active infections or a history of recurrent infections were not included in clinical trials. Upper respiratory infections occurred more frequently in the ILUMYA group than in the placebo group *[see Adverse Reactions]*.

The rates of serious infections for the ILUMYA group and the placebo group were ≤0.3%. Treatment with ILUMYA should not be initiated in patients with any clinically important active infection until the infection resolves or is adequately treated.

In patients with a chronic infection or a history of recurrent infection, consider the risks and benefits prior to prescribing ILUMYA. Instruct patients to seek medical help if signs or symptoms of clinically important chronic or acute infection occur. If a patient develops a clinically important or serious infection or is not responding to standard therapy, monitor the patient closely and consider discontinuation of ILUMYA until the infection resolves *[see Adverse Reactions]*.

**Pretreatment Evaluation for Tuberculosis:** Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with ILUMYA. Initiate treatment of latent TB prior to administering ILUMYA. In clinical trials, of 55 subjects with latent TB who were concurrently treated with ILUMYA and appropriate TB prophylaxis, no subjects developed active TB (during the mean follow-up of 56.5 weeks). One other subject developed TB while receiving ILUMYA. Monitor patients for signs and symptoms of active TB during and after ILUMYA treatment. Consider anti-TB therapy prior to initiation of ILUMYA in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Do not administer ILUMYA to patients with active TB infection.

**Immunizations:** Prior to initiating therapy with ILUMYA, consider completion of all age appropriate immunizations according to current immunization guidelines. Avoid the use of live vaccines in patients treated with ILUMYA. No data are available on the response to live or inactive vaccines.

**ADVERSE REACTIONS**
The following serious adverse reactions are discussed elsewhere in the labeling:
Hypersensitivity Reactions *[see Warnings and Precautions]*
Infections *[see Warnings and Precautions]*

**Clinical Trial 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.

In clinical trials, a total of 1994 subjects with plaque psoriasis were treated with ILUMYA, of which 1083 subjects were treated with ILUMYA 100 mg. Of these, 672 subjects were exposed for at least 12 months, 587 for 18 months, and 469 for 24 months.

Data from three placebo-controlled trials (Trials 1, 2, and 3) in 705 subjects (mean age 46 years, 71% males, 81% white) were pooled to evaluate the safety of ILUMYA (100 mg administered subcutaneously at Weeks 0 and 4, followed by every 12 weeks [Q12W]) *[see Clinical Studies]*.

Placebo-Controlled Period (Weeks 0-16 of Trial 1 and Weeks 0-12 of Trials 2 and 3)
In the placebo-controlled period of Trials 1, 2, and 3 in the 100 mg group, adverse events occurred in 48.2% of subjects in the ILUMYA group compared to 53.8% of subjects in the placebo group. The rates of serious adverse events were 1.4% in the ILUMYA group and 1.7% in the placebo group.

Table 1 summarizes the adverse reactions that occurred at a rate of at least 1% and at a higher rate in the ILUMYA group than in the placebo group.

**Table 1: Adverse Reactions Occurring in ≥1% of Subjects in the ILUMYA Group and More Frequently than in the Placebo Group in the Plaque Psoriasis Trials 1, 2, and 3**

| Adverse Reaction | ILUMYA 100 mg (N=705) N (%) | Placebo (N=355) N (%) |
|---|---|---|
| Upper respiratory infections* | 98 (14) | 41 (12) |
| Injection site reactions† | 24 (3) | 7 (2) |
| Diarrhea | 13 (2) | 5 (1) |

* Upper respiratory infections include nasopharyngitis, upper respiratory tract infection, viral upper respiratory tract infection, and pharyngitis.

† Injection site reactions include injection site urticaria, pruritus, pain, reaction, erythema, inflammation, edema, swelling, bruising, hematoma, and hemorrhage.

During the placebo-controlled period of Trials 1, 2, and 3, adverse reactions that occurred at rates less than 1% but greater than 0.1% in the ILUMYA group and at a higher rate than in the placebo group included dizziness and pain in extremity.

Specific Adverse Reactions
*Hypersensitivity Reactions*
Cases of angioedema and urticaria occurred in ILUMYA-treated subjects in clinical trials *[see Warnings and Precautions]*.

*Infections*
Infections were slightly more common in the ILUMYA group. The difference in frequency of infections between the ILUMYA group (23%) and the placebo group was less than 1% during the placebo-controlled period. The most common (≥1%) infections were upper respiratory infections. The rates of severe infections for the ILUMYA group and the placebo group were ≤0.3%.

*Safety Through Week 52/64*
Through Week 52 (Trials 1 and 3) and Week 64 (Trial 2), no new adverse reactions were identified with ILUMYA use and the frequency of the adverse reactions was similar to that observed during the placebo-controlled period.

**Immunogenicity**
As with all therapeutic proteins there is the potential for immunogenicity. 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 tildrakizumab in the studies described below with the incidences of antibodies in other studies or to other products may be misleading.

Up to Week 64, approximately 6.5% of subjects treated with ILUMYA 100 mg developed antibodies to tildrakizumab. Of the subjects who developed antibodies to tildrakizumab, approximately 40% (2.5% of all subjects receiving ILUMYA) had antibodies that were classified as neutralizing. Development of neutralizing antibodies to tildrakizumab was associated with lower serum tildrakizumab concentrations and reduced efficacy.

**DRUG INTERACTIONS**
**Live Vaccinations**
Avoid use of live vaccines in patients treated with ILUMYA *[see Warnings and Precautions]*.

**USE IN SPECIFIC POPULATIONS**
**Pregnancy:** Risk Summary
Limited available data with ILUMYA use in pregnant women are insufficient to inform a drug associated risk of adverse developmental outcomes. Human IgG is known to cross the placental barrier; therefore, ILUMYA may be transferred from the mother to the fetus. An embryofetal developmental study conducted with tildrakizumab in pregnant monkeys revealed no treatment-related effects to the developing fetus when tildrakizumab was administered subcutaneously during organogenesis to near parturition at doses up to 159 times the maximum recommended human dose (MRHD). When dosing was continued until parturition, a small increase in neonatal death was observed at 59 times the MRHD *[see Data]*. The clinical significance of this nonclinical finding is unknown.

All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. The background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Data: *Animal Data*

In an embryofetal developmental study, subcutaneous doses up to 300 mg/kg tildrakizumab were administered to pregnant cynomolgus monkeys once every two weeks during organogenesis to gestation day 118 (22 days from parturition). No maternal or embryofetal toxicities were observed at doses up to 300 mg/kg (159 times the MRHD of 100 mg, based on AUC comparison). Tildrakizumab crossed the placenta in monkeys.

In a pre- and postnatal developmental study, subcutaneous doses up to 100 mg/kg tildrakizumab were administered to pregnant cynomolgus monkeys once every two weeks from gestation day 50 to parturition. Neonatal deaths occurred in the offspring of one control monkey, two monkeys at 10 mg/kg dose (6 times the MRHD based on AUC comparison), and four monkeys at 100 mg/kg dose (59 times the MRHD based on AUC comparison). The clinical significance of these nonclinical findings is unknown. No tildrakizumab-related adverse effects were noted in the remaining infants from birth through 6 months of age.

**Lactation:** Risk Summary
There are no data on the presence of tildrakizumab in human milk, the effects on the breastfed infant, or the effects on milk production. Human IgG is known to be present in human milk. Tildrakizumab was detected in the milk of monkeys *[see Data]*.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ILUMYA and any potential adverse effects on the breastfed child from ILUMYA or from the underlying maternal condition.

**Pediatric Use:** Safety and effectiveness of ILUMYA in pediatric patients (<18 years of age) have not been established.

**Geriatric Use:** A total of 1083 subjects were exposed to ILUMYA 100 mg during Phase 2 and 3 trials. A total of 92 subjects were 65 years or older, and 17 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 and over is not sufficient to determine whether they respond differently from younger subjects.

**OVERDOSAGE:** In the event of overdosage, monitor the patient for any signs or symptoms of adverse reactions and administer appropriate symptomatic treatment immediately.

**PATIENT COUNSELING INFORMATION:** Advise the patient and/or caregiver to read the FDA-approved patient labeling (Medication Guide).

Instruct patients and/or caregivers to read the Medication Guide before starting ILUMYA therapy and to reread the Medication Guide each time the prescription is renewed. Advise patients of the potential benefits and risks of ILUMYA.

Hypersensitivity
Advise patients to seek immediate medical attention if they experience any symptoms of serious hypersensitivity reactions *[see Warnings and Precautions]*.

Infections
Instruct patients of the importance of communicating any history of infections to the doctor and contacting their doctor if they develop any symptoms of infection *[see Warnings and Precautions]*.

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SUN PHARMA

NOTES from your Office Manager

# The Use of Computers in Examination Rooms

## THE RISK:

The presence of laptops/tablets in examination rooms has become commonplace as more providers implement electronic health records. This method of documentation may place a barrier between the provider and the patient. Providers may miss non-verbal cues, and patients may perceive an electronic device as a hindrance to communication. In several recent medical malpractice cases, plaintiffs testified that the provider spent too much time entering information into the computer and not enough time listening. Utilizing effective communication skills to engage the patient while using a computer will enhance the integration of this technology into healthcare and improve the patient experience.

## RECOMMENDATIONS:

1. Analyze the examination room for placement of the computer. Position the computer in a way that enhances provider/patient communication. Consider using a cart on wheels to position the computer so that the provider faces the patient.
2. Establish eye contact with the patient and listen to his/her concerns before using the computer. Look at the patient while you speak.
3. Reassure the patient that you are listening to him/her.
4. Utilize the **POISED**[1] model:
   - **P** = **Prepare** for the visit.
   - **O** = **Orient** the patient to what you are doing.
   - **I** = **Information gathering** – allowing time for conversation.
   - **S** = **Share** what you are looking at on the screen with the patient.
   - **E** = **Educate** the patient, reinforce the plan of action.
   - **D** = **Debrief** and assess the degree to which the patient understands the recommendations and plan. Utilize the "teach-back method."
5. Print a copy of the visit for the patient and retain a copy in the patient's record (e.g., after-visit summary).
6. When computers remain in examination rooms, providers must log off at the completion of the encounter to protect patient privacy.

REFERENCES:

1. Frankel Ph.D., JAMA Internal Medicine commentary, November 30, 2015.

# Outside & Inside the 9 to 5...

## *How Abby Jacobson, PA-C Makes a Difference*

*The National Commission on Certification of Physician Assistants (NCCPA) has been spotlighting Certified PAs in the community who are making a difference. The goal was to celebrate the achievements of the profession and the individuals who exemplify the many ways Certified PAs have a positive impact on patients' lives every day. The chosen PAs embody what it means to be a Certified PA, demonstrating that when it comes to providing high quality health care, promoting wellness, impacting communities, and saving and changing lives…#PAsDoThat!*

*Our very own SDPA member and a former President, Abby Jacobson was one of the highlighted PAs. We congratulate Abby for the various ways she embodies what it truly means to be a PA making a difference.*

When physicians prepare for a pharmaceutical presentation or gather information to initiate a research study, they look to Abby Jacobson, PA-C, for her expertise. As the only Certified PA on a team of four physicians, four pharmacists, and one PhD researcher, Jacobson exemplifies why PAs are critical components in today's team-based healthcare model.

*Abby Jacobson, PA-C*

Jacobson showcased that "PAs know their stuff" in her role as a medical science liaison (MSL), a position typically occupied by physicians, PhDs, or pharmacists. She works in the medical affairs department of Ortho-Dermatologics where she provides medical expertise to physician thought leaders, presents scientific data on drug study design and results to physicians, PAs, and NPs, and facilitates investigator-initiated research. In October 2018, she was promoted to the position of medical director.

Before pivoting to medical research, Jacobson spent fifteen years working in dermatology at a private practice. "There's so much of my job I could not do without the clinical background," she said. "Without the experience I wouldn't be able to advise world-renowned physician leaders, prepare speakers at conferences to make sure they understand all content of presentations, or teach information to experts."

Abby has been a volunteer leader throughout her career. She was the first PA on the medical board of the National Psoriasis Foundation, President of the Society of Dermatology PAs, and a Director and House of Delegates representative for the Pennsylvania Society of PAs. She has also served as a committee chair for the National Eczema Association.

While engaged in leadership roles shaping PA practice, she's also been deeply committed to nurturing the next generation of PAs. For about thirteen years, she has served as a guest lecturer and preceptor for multiple PA programs including her most recent appointment at the Thomas Jefferson University PA program in Philadelphia. There, she encourages students to think beyond the classroom and fill roles that showcase what PAs can do with their advanced education.

"The best promotion of the profession is to take care of patients and encourage leadership,"

she said. "Seeing PAs in leadership roles made an impact on me as a student and early on in my career. I want to do the same for students and encourage them to broaden their skill sets. They can serve on university committees, medical boards, and write grant proposals. I want to make them think outside of their profession."

Her career trajectory underscores the elasticity of the profession. Now, as a Medical Director, she is demonstrating that PAs can bring advanced scientific and academic credentials to physicians and researchers working to ensure medications are safe and utilized effectively.

"Every day she shows that PAs have roles in all aspects of healthcare and fosters their leadership ambition," said colleague Archana M. Sangha, MMS, PA-C. "Abby believes deeply in helping create future leaders. She is so enthusiastic about the PA profession that it's contagious. She is the reason I am in PA leadership today."

For her accomplishments, Jacobson received a 2015 Inaugural Lifetime Achievement Award from the Society of Dermatology PAs, which recognizes leadership and significant contributions to strengthen the PA dermatology profession. However, there are a few more ambitious items to tackle on her bucket list. She's currently pursuing a PhD in public policy and healthcare administration and plans to expand her involvement in patient advocacy groups. And every new leap gets more satisfying, she said.

"I really love being a Certified PA and our profession," Jacobson said. "I'm proud of the role PAs can fill that are not related to direct patient care and want to see those opportunities continue to grow."

NCCPA salutes Abby Jacobson, PA-C, for championing PA leadership.

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# TOP 9 REASONS

# Dermatology PAs

*[or those PAs interested in dermatology]*

## Should Become a Member of the SDPA


*The largest of 26 specialty organizations under the American Academy of Physician Assistants (AAPA), the Society of Dermatology Physician Assistants (SDPA) is a non-profit professional association focused on empowering, educating and advancing PAs currently working in the field of dermatology and those who would like to work in the field.*

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BECOME A MEMBER

# Workplace Excellence

## *Do The Thing You Think You Can't, When You Don't Want To*

*By Matthew Davidson, PhD*

*In my work as President of the Institute for Excellence & Ethics (IEE) I have had the opportunity to work with diverse individuals and organizations in their quest to achieve excellence. This column dedicated to workplace excellence explores the organizational, interpersonal, and ethical issues that contribute to (or detract from) individual or organizational excellence within the physician assistant profession. If you have any workplace topics you would like to see covered in the JDPA please feel free to share them with us. Email editor@jdpa.org with any topic ideas or questions concerning the workplace.*

Eleanor Roosevelt famously said, "You must do the thing you think you cannot." I used to think of this quote in big picture terms: overcoming economic hardship, racism, war, or oppression. However, it has become for me a mantra and mindset for the development of mental toughness and fortitude, a guide for moment-to-moment decision-making that contributes to the development of mental toughness. This idea is a shoreline of sorts that I continue to wash upon; it provides sand that polishes the stone of my character.

Mental toughness comes down to doing the thing you think you cannot, which is mostly when you don't want to do it, or when there is an easier way around it. Most of us approach life waiting for the right time to present itself. When I'm well rested, well nourished; when the conditions are right, then I'll step up and perform. However, the best performers in every walk of life perform precisely when they are tired, hungry, hurting, and challenged to perform in less than ideal conditions and situations.

I've begun to keep a Mental Toughness Self-Study throughout the day. From the moment I wake up I begin to look for those things that I want or need to do and then observing what happens when I mobilize the willpower and grit to do them, and what happens when I don't. For example:

- Alarm rings: I want to/should get up, do I or not? If I do, what happens? If I don't, what happens?
- Out of bed now, I want to/should go for a run to strengthen my body and mind (which won't happen if I don't do it now): Do I go for the run or have another cup of coffee?
- On my run, I want to/should take the longer, more challenging route instead of the flatter, shorter, easier route, do I? What happens as a result of my action/inaction?

This may seem the mental wanderings of a neurotic freak, but here's what I have begun to see: initially as they present themselves every one of the opportunities evokes an "I can't do this now" mental reaction. I feel disempowered, tired, weak, and demoralized. I whine like a mental baby: "poor me, why do I always have to, nobody else has to, etc." I succumb to the compare-despair mindset: "so-and-so doesn't struggle with this; she's so smart; he's so rich; they've got it so easy compared to me." When I don't do what I should when I should, then the negative consequences and demoralization begin to accumulate: for example, I didn't workout when I had the chance, as a result I wasn't mentally sharp all day, my brain and legs got tired sooner, and I never got my workout in, which made it even tougher to do a run the next day.

However, when and if I do the thing I think I cannot when I don't want to, then I feel empowered, optimistic, I feel tough. I just got up on the first alarm when it was dark and cold out; I just ran nine hilly miles when I didn't think I was going to be able to drag my butt around the block. Each instance where I do what I thought I couldn't when I didn't want to gives me a feeling of empowerment, a tangible psychological asset for the next challenge I face: winning begets winning; objects in motion stay in motion. These don't have to be big things; in fact, they're often relatively speaking very little things.

At first glance, this approach may seem largely about me learning to develop the habit of doing what I want/need to do; in other words, personal responsibility. However, it has a very interesting interconnection with collective responsibility and a form of servant leadership. Let me share a few of my other day-to-day Mental Toughness Self-Study examples:

- In the kitchen getting the kids breakfast and the dishwasher is full, again! I could/should empty it, or leave it for my wife to do.
- Finally getting to sit down and watch the game after a long day, I could/should fold the kids' laundry while I watch the game (but darn if it isn't the basket of the kids' socks, which I hate).
- Got a task for a project that my colleagues are waiting on, I could/should do it, but there are easier ones that I'd prefer to do.

In each of these seemingly simple examples there is a challenge to mental toughness. In my choice I can choose to do the thing I don't want to do, or I can choose the easier path. My choice, however, is not simply about me; sure, whatever I choose will impact me, but those around me are also impacted. Others on my team, in my family and in my community become motivation for doing the thing I think I can't when I don't want to. They become motivation; my love for them, my desire to serve them can provide the extra edge I need for doing it, and the extra energy I get from doing it. I hate that the dishwasher always seems full, but I love showing my kids how to tough through tasks like this and so I pull them in and we rock it. I hate folding the kids' socks, but I love making my wife happy and removing a little burden for her. I hate some of the tasks at work that I have to do, but I love the feeling that comes from contributing my piece of a project that allows others to thrive. As demotivating and demoralizing as it can be to me personally to give in on a mental toughness challenge, it's double the impact when I realize how it lets down those I love and who put their trust in me.

Thus, I would argue that two main impediments to mental toughness are softness and selfishness. If you're soft, you don't do things that you don't want to do when you don't want to do them. You do the easy things, the fun things, the things you're good at. You are soft if you main modus operandi is "I do what I like when I feel like it." You are also selfish if you don't care that your decisions fail to contribute to the good of those around you. The selfish person cannot get past what they want, need, and feel. They cannot or will not sacrifice for the good of others.

There is no easy way to develop mental toughness; but there is a simple way to begin: do the next thing that you think you can't or simply don't want to. Just do it, and watch the positive impact on your attitude and confidence and those around you.

*Matthew L. Davidson, Ph.D. is the Founder, President, and Director of Education for the Institute for Excellence & Ethics (IEE), a 501(c)3 nonprofit corporation dedicated to helping individuals and organizations achieve excellence. He is a National Spokesperson for the Business Bureau National Center for Character Ethics. The IEE specializes in the development and dissemination of research-based tools for developing the culture and competencies of excellence and ethics in schools, athletics, the workplace, and the home; this is done through professional development workshops & academies, teaching & learning resources, assessment, and consulting services. He is a frequent national presenter and is available for keynote lectures, professional development, retreats, and organizational consulting. He has indicated no relationships to disclose relating to the content of this article. For additional information or to contact the IEE, please visit www.excellenceandethics.org.*

# Listening To Patients

## *The Chief Complaint*

*By Alan Rockoff, MD*

In medical school they taught us to learn the patient's chief complaint.

In dermatology the presenting complaint is on the outside, where the skin is. The chief complaint is often deeper.

SANDRA

I ask, "How are your parents?"

Sandra replies, "Getting older. I'm over at their house every day. It's always something. My husband had a stroke this year. Our daughter, she's a nurse, made him get help. 'You're not talking right,' she said to him. 'You're going to the hospital right now.'

"Stan's at home. He can't work construction anymore. When I get back from taking care of my parents, I take care of him."

Sandra's moles are normal. Who is taking care of her?

GRIGORIY

"I've had a hard life," says Grigoriy, apropos of nothing.

I ask, "How?"

"My father was important in the Communist party. Stalin purged him in 1938. I was a teenager. They kept me in a cell of one room for fifteen years."

I inquire, "Why did they put you in jail?"

"I was my father's son."

PHIL

Phil is in for his annual exam. He looks robust, but thinner.

"Sorry I missed last year," he says. "I was clearing my throat a lot. An ENT doctor found I had cancer of the vocal cords. I had 39 radiation sessions. They said I would handle them OK, but afterwards I'd feel awful. They were right. I lost twenty pounds," says Phil. "But now I'm getting back to myself." His smile is broad, but uncertain.

FRED

Fred's rash is impressive: big, purple blotches all over. Could be a drug eruption, only he takes no drugs.

"It may be viral," I say.

"Can I visit my dad in Providence Sunday?" he asks. "It's Father's Day."

"I'm not sure…." I say.

Fred says, "Dad has cancer of the esophagus. They're hoping that chemo may buy him a little time."

I tell Fred to wash carefully. Some things can't be rescheduled.

EMILY

Emily's Mom has left me a note to read before I see her daughter. It lists Emily's five psychoactive medications.

Emily is lying on her back and does not sit up. Her gaze is vague and unfocused.

Emily has moderate papular acne on her cheeks. That is her presenting complaint. It is not her chief complaint. As for what her mother goes through, I can barely imagine.

BRENDA

Brenda comes for six-monthly skin checks. Usually with her husband Glen, but not today.

"Glen's not so well," Brenda says. "The doctors diagnosed him with MS. They're vague about how fast it will progress. I guess they don't know. To tell the truth, Glen's pretty depressed. But he doesn't want to talk to anyone about it. Do you know a psychiatrist who specializes in MS patients? Glen might take your advice."

TOM

"It's been a tough year. Eddie died. You saw him years ago, I think." I actually remember Eddie. A troubled kid with terrible acne. He had one visit and never came back.

"I was walking in a mountain field in Cambodia when I got the word," says Tom. "My ex called me. 'Eddie died,' she said. 'Drug overdose. Come home.'

"Every year I walk through Cambodia and Myanmar for a month," says Tom. "Just to be alone. The people there are nice. They let me be."

"Eddie was a good boy. He hung with the wrong crowd. He made a mistake, and he could never get past it. I think of him every day."

FRANK

Frank doesn't pick. Frank gouges. He's been gouging his forearms for years. Intralesional steroids help a little. But he can't stop.

"I guess it's stress," Frank says.

"How about avoiding stress?" I ask, with a smile.

Frank breaks down and weeps.

"I'm sorry," he says. He gathers himself. "My wife has breast cancer. Mammogram showed a spot four years ago. Then it grew. It's already stage four. Our kids are teenagers."

Frank breaks down again. He apologizes again. "I'm so sorry for being like this," says. Again he weeps, again he apologizes. "I shouldn't act like this," he says. "I'm sorry."

I am sorry too. Very sorry indeed. Like all doctors, I want to help. Sometimes I can help the skin and temper the presenting complaint. But for patients' true chief complaints, often incidental to the superficial presenting ones, all I can do is listen. It's not much, but it's the best I can do. For many patients, over many years, listening has been the most I've had to offer.

***Alan Rockoff, MD*** *practices dermatology in Boston, MA. He graduated with his medical degree in 1972 from the Albert Einstein College of Medicine in New York and then completed a pediatric internship and residency at Bronx Municipal Hospital Center. Continuing his education, Dr. Rockoff completed a dermatology residency program at the combined program at Boston University and Tufts University. Dr. Rockoff is a Clinical Assistant Professor of Dermatology at Tufts University School of Medicine. He has taught senior medical students and other trainees for over thirty-five years.*

*Dr. Rockoff has been named one of Boston's Top Doctors by Boston Magazine for five years. Dr. Rockoff is board certified by the American Board of Pediatrics and the American Board of Dermatology. Dr. Rockoff is a Fellow of the American Academy of Dermatology and a member of the Massachusetts Medical Society and the Massachusetts Academy of Dermatology.*

*Dr. Rockoff's publications have appeared in a number of journals. He writes a monthly column for his dermatologic colleagues in Dermatology News as well as a blog for the magazine Psychology Today. His first book, "Under My Skin: A Dermatologist Looks at His Profession and His Patients" is available on Amazon and is his second book, "Act Like a Doctor, Think Like a Patient: Teaching Patient-focused Medicine" is available on Amazon and at Barnes and Noble.*

# From the Desk of...

*Mark Hyde, PHD, PA-C*
*Director of Advanced Practice Care*
*Huntsman Cancer Institute*

## A Critical Part of the Care Team: Advanced Practice Care Providers

Two years ago, I accepted the position of Director of Advanced Practice at the Huntsman Cancer Institute. My new position puts me in a number of new roles and is constantly changing. I work as an advocate, negotiator, listening ear, consultant, committee member, and colleague to more than ninety PAs and NPs. This role occupies four of my five working days. But I still love my 5th day, my clinical practice day the most. I've been treating some of my patients for more than a decade, so in some ways I think of them as family. My wife notices when I get home on Friday, which is my clinic day, that I'm usually in a good mood. It's not because it is the beginning of the weekend, but because I got to spend the day with patients.

### ON THE CLINICAL SIDE:

Working with cancer patients is something I didn't understand before I came to Huntsman Cancer Institute. But now, I would never go anywhere else, because they are a unique population, they are easy to want to help.

*"Anyone who participates in a cancer patient's care is privileged to be in that intimate space with them." - Mark Hyde*

One of my patients explained to me that the cancer experience is very personal. When I talk to patients about cancer and their health, it is a very intimate space the patients are trusting me to come into. In Mohs surgery this is particularly true. It is not uncommon for these patients to spend the entire day in our clinic. And, while their cancers are usually not life threatening, I've learned how anxiety and stress inducing Mohs surgery can be. It is so important to manage their anxiety and expectations.

Working in this type of a clinic requires a very inclusive team based approach. I have been lucky to learn from one of the best mentors in Mohs surgery. Dr. Glen Bowen taught me that the treatment team is like an octopus. We are a single brain with a number of arms. I'm an arm, the nurse is an arm, the scheduler is an arm, we are all an arm, and no arm is more or less important in caring for our patients. If all arms are communicating and integrated, the patients' experiences and outcomes are good.

### AS AN ADMINISTRATOR:

I think the challenges I face are the challenges that all PAs face to some extent. Foremost is the question of the right level of autonomy. My experience suggests that dermatology PAs enjoy a decent amount of autonomy in most practices. As I have worked on increasing autonomy in practice, I have slowly began to understand that the onus is mostly on the individual PA. In many conversations concerning autonomy, I have found physicians willing to grant more autonomy based on the merits of the PA. Other times physicians have not felt a need or a desire for more autonomy even when practice data suggests it is needed. A PA hoping to increase autonomy should focus on specialty specific education and training and make sure their SP is aware of the education and training. They should have regular meetings or discussions with their SP about how they can increase trust, prove acumen, and increase autonomy. In the end, PAs have to remember that the SP is ultimately responsible and autonomy must be earned. Sometimes, the level of autonomy desired by the PA and granted by the SP can't be aligned; in these circumstances, a change of position may be needed.

The advanced practice clinicians (APCs) at Huntsman Cancer Institute (HCI) include licensed care providers, such as nurse practitioners or physician assistants. Educational programs that train APCs typically require several years of prior health care experience and at least two years of full-time post-graduate medical education. HCI has invested in APCs, knowing that this group of talented medical professionals is a critical link in the cancer care continuum.

# Collaborating Physician **CORNER**

## The Dermatologist/PA Team

Physician Assistants (PAs) are licensed by all 50 states to practice medicine in collaboration with a physician. Each state has some sort of practice plan or collaboration agreement that allows the team to outline how they will work together to care for patients. This collegial relationship promotes quality patient care fostering a team approach to health care delivery. The services provided by the PA are determined by the collaborating physician based on the knowledge, training and skills of the PA and necessarily reflects the practice style and services provided by the dermatologist. Each state requires that a PA scope of practice mirrors that of the physician. The experience and skills of the PA will increase over time and the practice plan should allow for those changes or should be updated as needed.

### PHYSICIANS

The Society of Dermatology Physician Assistants (SDPA) would like to welcome you to our official website. If you are a visiting dermatologist, we sincerely hope that you will find the information you are looking for. The SDPA was created to serve the needs of PAs specializing in dermatology. We are honored to be the largest specialty PA organization. We owe this to the physicians who have given us the opportunity to share in the care of their patients. Therefore, we also desire to provide a service to dermatologists, especially those who serve as our collaborating physicians. Currently, there are over 100,000 PA graduates. There are well over 3,000 PAs specializing in dermatology and the AAD estimates that approximately 50% of dermatologists currently employ a PA. We hope you are one of them! If not, we hope you are interested in adding a PA to your practice. We are here to help you through that process. We have developed a website, www.hireadermpa.org, to provide dermatologists with information regarding the training, education and utilization of PAs. It also provides an opportunity to place a job listing for a PA and search member resumes. Dermatologists who currently supervise a PA are offered complimentary membership to the SDPA and enjoy benefits such as a subscription to our Journal of Dermatology for Physician Assistants (JDPA), a physician newsletter relating to PA practice, contract & compensation information, access to a document library, and much more. Please take a moment to see for yourself what the SDPA has to offer to our physician colleagues.

JDPA Journal of Dermatology for Physician Assistants

**INFORMATION FOR AUTHORS** – The JDPA is a peer-reviewed publication that delivers innovative clinical, surgical, cosmetic, and professional content exclusively for dermatology PAs. Submissions to the JDPA are peer-reviewed by a panel of experienced dermatology PAs, educational PAs, and dermatologists before articles are accepted for publication.

Manuscripts submitted for publication will be reviewed with the understanding that they are original and have not been submitted elsewhere nor are being considered by other journals. Electronic submissions are accepted and should be sent to editor@jdpa.org.

The five main sections featured in each issue of the JDPA are listed below along with a brief description of the various topics that authors can contribute to. Regardless of the section, all articles must follow the following criteria:

- ***Formatting*** - Times New Roman font, 12 point, double-spaced, left aligned.
- ***Article Order*** - Title, Author(s), Author bios (including disclosures), Text of Article, References, Tables, and Figures
- ***Reference Citations*** - Utilize the AMA Manual of Style, 10th Edition.

## DERMATOLOGY PA NEWS AND NOTES

### Feature Articles

Write a review about a new or innovative dermatological procedure, device, and/or approach to patient care (500-1000 words).

### From The Desk Of…

Write an opinion essay sharing your insight regarding a current "hot item" issue *(e.g., specialty PA credentialing, dermatology access to care, supervising physician relationships, etc.)* or any other topic regarding the field of dermatology (250-1000 words).

## CLINICAL DERMATOLOGY

### CME articles

Content should be specific to the field of dermatology following any of the following formats:

Study – Original research (clinical or basic science).
Professional issues or health policy papers.
Review – Scholarly review of a topic.

Content length:

6 pages (requires 4 self-assessment Q&A) = .5hr of Cat. I CME.
12 pages (requires 8 self-assessment Q&A) = 1hr of Cat. I CME.

Article should include written learning objectives (3-4 required).

### Dermatology Case Report

Write a report and discuss a case(s) that illustrate an important or interesting observation (500-1500 words).

### Journal Club: Dermatology PA Perspectives

Write a review of an already published article from an established dermatology journal *(e.g., JAAD, Cos Dermatol, Dermatol Surg, etc.),* summarizing the practical thoughts and clinical issues (250-1000 words).

### From the Patient's Perspective

Patients' stories published in their own words. JDPA staff can even assist patients with writing their stories (250-1000 words).

### Clinical Snapshots

Write a brief written description and clinical facts about an interesting cutaneous anomaly (250-500 words).

### Drugs in Dermatology

Write about the current information regarding a particular dermatological medication, drug interaction, or medication side effect/adverse reaction (250-1000 words).

### Dermatology Evidence-Based Medicine (derm EBM)

Write a brief, evidence-based assessment of the one or two most relevant studies retrieved to answer a focused clinical question that may have arisen from a real-life situation. A derm EBM is not a comprehensive review of a subject or a synthesis of all the available knowledge (500–1500 words).

## SURGICAL DERMATOLOGY

### Feature Articles

Write a review about a new or innovative surgical procedure, device, and/or approach to patient care (500-1000 words).

### Surgical Wisdom

Write a brief article on a fact or pearl for the surgical setting (250-500 words).

### Surgical Dermatology Case Report

Write a report and discuss a case(s) that illustrate an important or interesting observation (500-1500 words).

### Journal Club: Dermatology PA Perspectives

Write a review of an already published article from an established dermatology journal *(e.g., JAAD, Cos Dermatol, Dermatol Surg, etc.),* summarizing the practical thoughts and clinical issues (250-1000 words).

## COSMETIC DERMATOLOGY

### Feature Articles

Write a review about a new or innovative cosmetic procedure, device, and/or approach to patient care (500-1000 words).

### Cosmetic Pearls

Write a brief article on a fact or pearl for the cosmetic setting (250-500 words).

### Cosmetic Dermatology Case Report

Write a report and discuss a case(s) that illustrate an important or interesting observation (500-1500 words).

### Journal Club: Dermatology PA Perspectives

Write a review of an already published article from an established dermatology journal *(e.g., JAAD, Cos Dermatol, Dermatol Surg, etc.),* summarizing the practical thoughts and clinical issues (250-1000 words).

## PROFESSIONAL DEVELOPMENT

### Feature Articles

Write an article that explores the professional issues dermatology PAs face such as reimbursement, education, medical trends, contracts, office management, etc. (500-1500 words).

### Outside & Inside the 9 to 5

Allow us to share your story of the good work that you do either outside or inside your practice of dermatology. You can write this article yourself or the JDPA staff can interview you to write the article (250-1000 words). **Notes From Your Office Manager**
Write a brief article on a fact or pearl for the office setting (250-500 words).

### Judicial and Ethical Affairs

Write an article that explores the complex or multifaceted ethical or judicial professional issues that affect the practice of dermatology for PAs (250-1000 words).

To read the JDPA publication's Ethics and Malpractice Statement, please visit www.jdpa.org/write.html.

## ADVERTISER **INDEX**



*For more information on advertising opportunities in the JDPA, please log on to www.jdpa.org*

**BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION**

**This Brief Summary does not include all the information needed to use ONEXTON Gel safely and effectively. See full prescribing information for ONEXTON Gel.**

**ONEXTON® (clindamycin phosphate and benzoyl peroxide) Gel, 1.2%/3.75%, for topical use**

**Initial U.S. Approval: 2000**

## CONTRAINDICATIONS

### Hypersensitivity

ONEXTON Gel is contraindicated in those individuals who have shown hypersensitivity to clindamycin, benzoyl peroxide, any components of the formulation, or lincomycin. Anaphylaxis, as well as allergic reactions leading to hospitalization, has been reported in postmarketing use with ONEXTON Gel *[see Adverse Reactions]*.

### Colitis/Enteritis

ONEXTON Gel is contraindicated in patients with a history of regional enteritis, ulcerative colitis, or antibiotic-associated colitis *[see Warnings and Precautions]*.

## WARNINGS AND PRECAUTIONS

### Colitis

Systemic absorption of clindamycin has been demonstrated following topical use of clindamycin. Diarrhea, bloody diarrhea, and colitis (including pseudomembranous colitis) have been reported with the use of topical and systemic clindamycin. If significant diarrhea occurs, ONEXTON Gel should be discontinued.

Severe colitis has occurred following oral and parenteral administration of clindamycin with an onset of up to several weeks following cessation of therapy. Antiperistaltic agents such as opiates and diphenoxylate with atropine may prolong and/or worsen severe colitis. Severe colitis may result in death.

Studies indicate toxin(s) produced by Clostridia is one primary cause of antibiotic-associated colitis. The colitis is usually characterized by severe persistent diarrhea and severe abdominal cramps and may be associated with the passage of blood and mucus. Stool cultures for *Clostridium difficile* and stool assay for *C. difficile* toxin may be helpful diagnostically.

### Ultraviolet Light and Environmental Exposure

Minimize sun exposure (including use of tanning beds or sun lamps) following drug application *[see Nonclinical Toxicology]*.

## ADVERSE REACTIONS

The following adverse reaction is described in more detail in the Warnings and Precautions section of the label:

Colitis *[see Warnings and Precautions]*.

### Clinical Trials Experience

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

These adverse reactions occurred in less than 0.5% of subjects treated with ONEXTON Gel: burning sensation (0.4%); contact dermatitis (0.4%); pruritus (0.4%); and rash (0.4%).

During the clinical trial, subjects were assessed for local cutaneous signs and symptoms of erythema, scaling, itching, burning and stinging. Most local skin reactions either were the same as baseline or increased and peaked around week 4 and were near or improved from baseline levels by week 12. The percentage of subjects that had symptoms present before treatment (at baseline), during treatment, and the percent with symptoms present at week 12 are shown in Table 1.

**Table 1: Local Skin Reactions - Percent of Subjects with Symptoms Present. Results from the Phase 3 Trial of ONEXTON Gel 1.2%/3.75% (N = 243)**

| | Before Treatment (Baseline) | | | Maximum During Treatment | | | End of Treatment (Week 12) | | |
|---|---|---|---|---|---|---|---|---|---|
| | Mild | Mod.* | Severe | Mild | Mod.* | Severe | Mild | Mod.* | Severe |
| Erythema | 20 | 6 | 0 | 28 | 5 | <1 | 15 | 2 | 0 |
| Scaling | 10 | 1 | 0 | 19 | 3 | 0 | 10 | <1 | 0 |
| Itching | 14 | 3 | <1 | 15 | 3 | 0 | 7 | 2 | 0 |
| Burning | 5 | <1 | <1 | 7 | 1 | <1 | 3 | <1 | 0 |
| Stinging | 5 | <1 | 0 | 7 | 0 | <1 | 3 | 0 | <1 |

*Mod. = Moderate

### Postmarketing Experience

Because postmarketing adverse reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Anaphylaxis, as well as allergic reactions leading to hospitalizations, has been reported in postmarketing use of products containing clindamycin phosphate/benzoyl peroxide.

## DRUG INTERACTIONS

### Erythromycin

Avoid using ONEXTON Gel in combination with topical or oral erythromycin-containing products due to its clindamycin component. In vitro studies have shown antagonism between erythromycin and clindamycin. The clinical significance of this in vitro antagonism is not known.

### Concomitant Topical Medications

Concomitant topical acne therapy should be used with caution since a possible cumulative irritancy effect may occur, especially with the use of peeling, desquamating, or abrasive agents. If irritancy or dermatitis occurs, reduce frequency of application or temporarily interrupt treatment and resume once the irritation subsides. Treatment should be discontinued if the irritation persists.

### Neuromuscular Blocking Agents

Clindamycin has been shown to have neuromuscular blocking properties that may enhance the action of other neuromuscular blocking agents. ONEXTON Gel should be used with caution in patients receiving such agents.

## USE IN SPECIFIC POPULATIONS

### Pregnancy

Pregnancy Category C.

There are no adequate and well-controlled studies in pregnant women treated with ONEXTON Gel. ONEXTON Gel should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Animal reproductive/developmental toxicity studies have not been conducted with ONEXTON Gel or benzoyl peroxide. Developmental toxicity studies of clindamycin performed in rats and mice using oral doses of up to 600 mg/kg/day (240 and 120 times amount of clindamycin in the highest recommended adult human dose based on mg/m$^2$, respectively) or subcutaneous doses of up to 200 mg/kg/day (80 and 40 times the amount of clindamycin in the highest recommended adult human dose based on mg/m$^2$, respectively) revealed no evidence of teratogenicity.

### Nursing Mothers

It is not known whether clindamycin is excreted in human milk after topical application of ONEXTON Gel. However, orally and parenterally administered clindamycin has been reported to appear in breast milk. Because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to use ONEXTON Gel while nursing, taking into account the importance of the drug to the mother.

### Pediatric Use

Safety and effectiveness of ONEXTON Gel in pediatric patients under the age of 12 have not been evaluated.

### Geriatric Use

Clinical trials of ONEXTON Gel did not include sufficient numbers of subjects aged 65 and older to determine whether they respond differently from younger subjects.

## NONCLINICAL TOXICOLOGY

### Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenicity, mutagenicity and impairment of fertility testing of ONEXTON Gel have not been performed.

Benzoyl peroxide has been shown to be a tumor promoter and progression agent in a number of animal studies. Benzoyl peroxide in acetone at doses of 5 and 10 mg administered topically twice per week for 20 weeks induced skin tumors in transgenic Tg.AC mice. The clinical significance of this is unknown.

Carcinogenicity studies have been conducted with a gel formulation containing 1% clindamycin and 5% benzoyl peroxide. In a 2-year dermal carcinogenicity study in mice, treatment with the gel formulation at doses of 900, 2700, and 15000 mg/kg/day (1.8, 5.4, and 30 times amount of clindamycin and 2.4, 7.2, and 40 times amount of benzoyl peroxide in the highest recommended adult human dose of 2.5 g ONEXTON Gel based on mg/m$^2$, respectively) did not cause any increase in tumors. However, topical treatment with a different gel formulation containing 1% clindamycin and 5% benzoyl peroxide at doses of 100, 500, and 2000 mg/kg/day caused a dose-dependent increase in the incidence of keratoacanthoma at the treated skin site of male rats in a 2-year dermal carcinogenicity study in rats. In an oral (gavage) carcinogenicity study in rats, treatment with the gel formulation at doses of 300, 900 and 3000 mg/kg/day (1.2, 3.6, and 12 times amount of clindamycin and 1.6, 4.8, and 16 times amount of benzoyl peroxide in the highest recommended adult human dose of 2.5 g ONEXTON Gel based on mg/m$^2$, respectively) for up to 97 weeks did not cause any increase in tumors. In a 52-week dermal photocarcinogenicity study in hairless mice, (40 weeks of treatment followed by 12 weeks of observation), the median time to onset of skin tumor formation decreased and the number of tumors per mouse increased relative to controls following chronic concurrent topical administration of the higher concentration benzoyl peroxide formulation (5000 and 10000 mg/kg/day, 5 days/week) and exposure to ultraviolet radiation.

Clindamycin phosphate was not genotoxic in the human lymphocyte chromosome aberration assay. Benzoyl peroxide has been found to cause DNA strand breaks in a variety of mammalian cell types, to be mutagenic in *S. typhimurium* tests by some but not all investigators, and to cause sister chromatid exchanges in Chinese hamster ovary cells.

Fertility studies have not been performed with ONEXTON Gel or benzoyl peroxide, but fertility and mating ability have been studied with clindamycin. Fertility studies in rats treated orally with up to 300 mg/kg/day of clindamycin (approximately 120 times the amount of clindamycin in the highest recommended adult human dose of 2.5 g ONEXTON Gel, based on mg/m$^2$) revealed no effects on fertility or mating ability.

## PATIENT COUNSELING INFORMATION

*See FDA-approved patient labeling (Patient Information).*

Manufactured for:
Valeant Pharmaceuticals North America LLC
Bridgewater, NJ 08807 USA
By:
Valeant Pharmaceuticals International, Inc.
Laval, Quebec H7L 4A8, Canada
U.S. Patent 8,288,434

Rev 04/2018
9432703
ONX.0081.USA.18

Ortho | Dermatologics

# ALL ABOARD ONEXTON GEL

**Efficacy and tolerability matter when it comes to treating acne. In the pivotal trial, ONEXTON GEL was shown to treat both inflammatory and noninflammatory acne, and no patients discontinued due to an adverse event.[1,2]**


**INSTANT SAVINGS FOR ELIGIBLE PATIENTS AT ORTHORXACCESS.COM**
TERMS AND CONDITIONS APPLY

## INDICATION

ONEXTON (clindamycin phosphate and benzoyl peroxide) Gel, 1.2%/3.75% is indicated for the topical treatment of acne vulgaris in patients 12 years of age or older.

## IMPORTANT SAFETY INFORMATION

- ONEXTON Gel is contraindicated in patients with a known hypersensitivity to clindamycin, benzoyl peroxide, any component of the formulation, or lincomycin.
- ONEXTON Gel is contraindicated in patients with a history of regional enteritis, ulcerative colitis, or antibiotic-associated colitis.
- Diarrhea, bloody diarrhea, and colitis (including pseudomembranous colitis) have been reported with the use of topical and systemic clindamycin. ONEXTON Gel should be discontinued if significant diarrhea occurs.
- Orally and parenterally administered clindamycin has been associated with severe colitis, which may result in death.
- Anaphylaxis, as well as other allergic reactions leading to hospitalizations, has been reported in postmarketing use of products containing clindamycin/benzoyl peroxide. If a patient develops symptoms of an allergic reaction such as swelling and shortness of breath, they should be instructed to discontinue use and contact a physician immediately.
- The most common local adverse reactions experienced by patients in clinical trials were mild and moderate erythema, scaling, itching, burning and stinging.
- ONEXTON Gel should not be used in combination with erythromycin-containing products because of its clindamycin component.
- ONEXTON Gel should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. A decision should be made whether to use ONEXTON Gel while nursing, taking into account the importance of the drug to the mother.
- Patients should be advised to avoid contact with the eyes or mucous membranes.
- Patients should minimize exposure to natural and avoid artificial sunlight (tanning beds or UVA/B treatment) while using ONEXTON Gel. To minimize exposure to sunlight, protective clothing should be worn and a sunscreen with SPF 15 rating or higher should be used.

To report SUSPECTED ADVERSE REACTIONS, contact Ortho Dermatologics at 1-800-321-4576 or FDA at 1-800-FDA-1088 or visit www.fda.gov/medwatch.

**Please see Brief Summary of full Prescribing Information on the following page.**

**References: 1.** ONEXTON [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC. **2.** Pariser DM, Rich P, Cook-Bolden FE, Korotzer A. An aqueous gel fixed combination of clindamycin phosphate 1.2% and benzoyl peroxide 3.75% for the once-daily treatment of moderate to severe acne vulgaris. *J Drugs Dermatol.* 2014;13(9):1083-1089.

## LEARN MORE AT ONEXTON.COM



ONEXTON®
(clindamycin phosphate and benzoyl peroxide)
Gel, 1.2%/3.75%