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PART 2

Avoiding Liability in Telemedicine: HIPAA & Informed Consent

That you are a responsible covered entity under HIPAA and a fiduciary for the privacy of your patients' PHI do not decrease with telemedicine. In fact, it is a setting in which you want to be very careful, particularly if working from home, where family will be present and habits may become lax. Your primary obligation is to make sure no unauthorized individual encounters PHI in any form.

However, the Office of Civil Rights (OCR) will waive penalties for HIPAA violations that would otherwise accrue due to this issue during the COVID-19 crisis. The intention is to open a telehealth option to practitioners who were not set up for such but who find themselves with patients in need of any telehealth diagnostic or treatment, even if not directly related to coronavirus.

The OCR extended permissible use to non-public-facing apps such as Skype, Google Hangouts video, and Zoom, that only allow intended parties to participate. A Business Associates Agreement is not required.

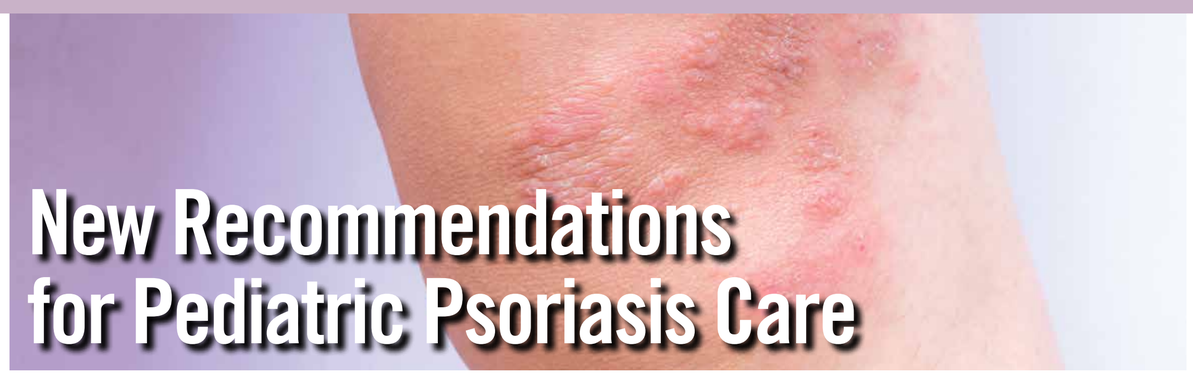
The standard during this waiver is one of good faith. If PHI is intercepted during transmission but the practitioner followed the OCR's guidance, there will be no penalty. Note, however, that states often have stricter regulations, and the federal waiver does not affect these.

Increased access also carries the important responsibility of informed consent. Many states specifically require that it be done and documented before engaging in a telehealth visit. In most such states, verbal consent is allowed, but consent must be obtained in writing in some. Regardless, the more certain the proof of consent, the better.

You should first inform the patient that this method is limited as compared with an in-person evaluation and is also potentially not secure. You should then get an affirmative consent to continue. If possible, build the consent form into the software so that the patient is required to assent before the virtual visit. If that is not possible, create a standardized e-mail with the consent and have the patient return it before you start. A verbal consent, if permissible, should be carefully documented.

You must apply all encryption and privacy modes available from your end. Increasing usable systems to ones that are inherently less secure is predicated on you doing what you can to minimize the risk of a breach, and it is this that the OCR will look to in determining a "good faith" use of the waiver. If a relative or friend or caregiver will be involved to help the patient with the televisit, make certain that you have a release that allows them access to PHI. Remember that the waiver on non-HIPAA compliant systems will only last during the emergency.

This article was written by Dr. Medlaw, a physician and medical malpractice attorney.



New Recommendations for Pediatric Psoriasis Care

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Although one-third of diagnosed cases of psoriasis are pediatric, clinical guidelines addressing the unique physiology, treatments, and patient-parent-provider interactions experienced by pediatric patients with psoriasis have not previously existed. To fill this void, the American Academy of Dermatology (AAD) and the National Psoriasis Foundation (NPF) co-developed a guideline for the management and treatment of psoriasis in pediatric patients, published in the *Journal of the American Academy of Dermatology*. "We know that the incidence of pediatric psoriasis increases with increasing age, making the need for guidelines of care for the management and treatment of psoriasis in pediatric patients an important asset for dermatologists, their pediatric patients, and their patients' families and caregivers," explains guideline co-chair Alan Menter, MD.

A multidisciplinary workgroup of dermatologists (including pediatric dermatologists), a rheumatologist, a cardiologist, and representatives from a patient advocacy organization with expertise in psoriasis was formed to develop the recommendations. Dr. Menter cites that "Pediatric Psoriasis: Evolving Perspectives" by Amy Paller, MD, et al, was a catalyst for the development of the guidelines. "The guideline gives dermatologists access to the latest recommendations on all forms of therapy for children, including topicals, phototherapies, systemic therapies, and biologic therapies," emphasizes Dr. Menter.

Triggers

The recommendations in the guideline highlight the multitude of triggers of psoriasis in pediatric patients, including emotional stress, increased body mass index, second-hand cigarette smoke, pharyngeal and perianal group A β-hemolytic Streptococcus infection, Kawasaki disease, and withdrawal of systemic corticosteroids (Table). Since the triggers for pediatric patients are broad, Dr. Menter recommends "a robust physician-patient-caregiver relationship to facilitate a collaborative decision-making model."

Comorbidities

As with adults, pediatric patients with psoriasis are at risk for numerous comorbidities that could affect their overall health and quality of life. Common comorbidities for pediatric patients with psoriasis include arthritis, heart disease, dyslipidemia, obesity, metabolic syndrome, and depression (Table).

Dr. Menter highlights the emotional impact psoriasis can have on pediatric patients. "The guideline goes a step further than providing recommendations for common clinical questions that arise among physicians, patients, and caregivers in psoriasis management," he says; "they address the emotional toll that psoriasis has on pediatric patients, many of whom are bullied and teased by their peers. Pediatric and clinical dermatologists alike must recognize the mental health aspect that is common among children and adolescents, because it is equally important to address the emotional and physical symptoms pediatric patients can face on a day-to-day basis."

More to Come

Dr. Menter believes there is more to be done for pediatric patients with psoriasis now that the guideline has been published. "We still have some work to do and research to uncover to better and fully understand how such systemic and biologic therapies work in children and adolescent patients with psoriasis."

Table Summarizing Trigger & Comorbid Condition Recommendations

Recommendation	Strength
Pediatric patients with psoriasis should be educated about the risk of PSA and its clinical manifestations.	C
Pediatric patients with psoriasis should be routinely screened for PSA via a thorough history and physical examination.	C
Pediatric patients with psoriasis who show signs and symptoms of inflammatory arthritis should be referred to a rheumatologist with pediatric expertise, if available, for further evaluation and management.	C
Pediatric psoriasis patients with PSA should be routinely screened for uveitis by history and physical examination.	C
Pediatric patients with psoriasis who show signs and symptoms of uveitis should be referred to an ophthalmology specialist for further evaluation and management.	C
Pediatric patients with psoriasis should be routinely assessed for obesity.	B
Pediatric psoriasis patients with obesity should be routinely assessed for the comorbidities of obesity (independent of psoriasis).	B
Pediatric patients with psoriasis and their families should be educated about the increased risk of cardiovascular disease.	C
Pediatric patients with psoriasis and their parents should be screened for cardiovascular risk factors when history and physical examination findings show a potential risk.	B
Pediatric patients with psoriasis who have been identified as having cardiovascular risk factors, such as obesity, dyslipidemia, diabetes, hypertension, or metabolic syndrome, should be referred to appropriate specialists for further evaluation and management.	C
Pediatric patients with psoriasis should be educated about their increased risk of dyslipidemia.	C
Pediatric patients with psoriasis should be screened for dyslipidemia between ages 9 and 11 years and 17 and 21 years, as recommended by the AAP for all children.	B
Pediatric psoriasis patients with increased risk for dyslipidemia may be screened more frequently at the provider's discretion.	C
Pediatric psoriasis patients with dyslipidemia should be referred to their primary care provider or an endocrinologist for further assessment and management.	C
In accordance with the AAP screening guidelines, pediatric patients with psoriasis aged 3 years and older should be screened annually for hypertension.	B
Pediatric patients with psoriasis should be educated about the potential association between psoriasis, insulin resistance, and diabetes mellitus.	C
Pediatric patients with psoriasis who are obese should be screened for insulin resistance and diabetes every 3 years at the onset of puberty or age 10 years, whichever is sooner.	C
Pediatric patients with psoriasis who are overweight and have increased risk for insulin resistance may be screened similarly to obese patients at the provider's discretion.	C
Pediatric psoriasis patients with insulin resistance or diabetes mellitus should be referred to their primary care provider or an endocrinologist for further assessment and management.	C
Pediatric patients with psoriasis should be screened routinely for mental health diseases, including depression and anxiety, regardless of age.	C
Pediatric patients with psoriasis should be asked about substance abuse.	C
Pediatric patients with psoriasis found to have mental health or substance abuse concerns should be referred to an appropriate healthcare professional for further assessment and management.	C
Pediatric patients with psoriasis who show signs and symptoms of inflammatory bowel disease should be considered for consultation with a gastroenterologist with pediatric expertise, if available, for further evaluation and management.	C

Abbreviation: PSA, psoriatic arthritis

Source: Adapted from: Menter A, et al. *J Am Acad Dermatol.* 2020;82(1):161-201.

33 CHARTS

Refusing Telemedicine – Can Patients Opt-out of Remote Care?

With the sweeping rise of COVID-19, telemedicine has taken healthcare by storm. During the local surges, this served as a mandated way of maintaining safe distancing. But as things come back to a new normal and as we decide where telemedicine fits in to a clinic structure, it might be worth asking: should patients have the option for in-person care? Is refusing telemedicine in favor of being physically seen a choice patients should be able to make? As we begin to settle in to a fixed role for telemedicine in the post-COVID world, centers are beginning to shape processes around telehealth.

Three assumptions that we make about patients and virtual encounters give shape to our policies:

ASSUMPTION OF APPROVAL

We assume that telemedicine is what patients prefer. The belief that patients prefer to be cared for in the context of their home isn't always the case. There may be sensitive issues or a hidden agenda that doesn't show well across a screen.

ASSUMPTION OF EQUIVALENCE

We assume that telemedicine is as good as in-person care. There is a bias to try to assess virtually some conditions that may best be assessed in real life. But, sometimes, medicine needs to be inconvenient.

ASSUMPTION OF CAPACITY

We assume the patient is able to participate in a virtual visit. Some families lack Internet access and equipment to complete a telemedicine visit. Tech insecurity is a bigger issue than thought initially when we started doing telemedicine.

There are many reasons why a patient may prefer an in-person visit. Our assumptions about the magic of telemedicine are not always right. While we should work to accommodate the preferences of the patient, patients need to understand that there are conditions and circumstances where an in-person visit is not necessary. And patients should be offered the right of refusing telemedicine.

Will our telemedicine policies pull us back to an imbalanced doctor-patient relationship? After the COVID dust falls, we need to create more structure that respects the interests and will of the patient. Telemedicine is a moving target. What works or doesn't work today may have a very different solution or experience a year from now. Flexibility and rapid reiteration of our processes will be critical to successful adjustment and growth.

Visit 33charts.com to read the full article.

The Pros & Cons of Facebook Use Among Patients With Psoriasis

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"Prior research suggests that using Facebook can be both beneficial and harmful for well-being," explains Barbara Schuster, MSc. Although interaction with other users with the condition could be a beneficial source of social support for patients with psoriasis, use of Facebook can also be mentally straining, as users tend to share only the highlights of their lives. To understand how people with psoriasis use Facebook and to assess potential risks of such use, Schuster and colleagues developed an online survey, the results of which are published in the *Journal of The German Society of Dermatology*.

The survey was promoted and provided on a large psoriasis information website. Data was collected on participants' general and disease-related Facebook habits, with questions analyzing frequency and duration of Facebook use, dermatology-specific quality of life (DLQI), frequency of searching Facebook for disease-related information, quality of disease-related information found, participation in disease-related groups, and whether Facebook helped participants in managing their condition.

Results indicated that 75% of participants used Facebook in the previous month, with 57% spending 5 to 30 minutes on the platform daily. Higher DLQI was associated with less time spent on Facebook. Of Facebook users aged 60 and older, 92% used the platform to search for disease-related information, whereas only 52% of users aged 30 and younger used the platform as a source for such information. "We found that sharing experiences with other affected individuals seems to help patients cope with their disease," notes Schuster. "However, the quality of psoriasis-related content on Facebook seems to be insufficient, as only 19% of users thought the platform provided sufficient information. As a consequence, most users seem rather skeptical toward Facebook as a source of disease-related information."

"Facebook has mostly been neglected in health service research so far, which might be one of the reasons for the lack of high-quality content available," says Schuster. "We would like physicians to keep in mind that social media can offer more than information to patients with chronic diseases, like social support. Also, we think social media should be accepted and explored as a potential means of delivering healthcare information and services in future healthcare research."

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At Week 28, responders were re-randomized to 100 mg, 200 mg, or treatment withdrawal, and non-responders (14.4%) were discontinued from therapy. Data represents recommended 100 mg group.[1,2]

*From a pooled analysis of reSURFACE 1 and 2. Conducted with non-responder imputation.

†AEs of interest include: serious infections, malignancies, non-melanoma skin cancer, melanoma, extended MACE, deaths, injection site reactions, and drug-related hypersensitivity AEs.

AE=adverse event; MACE=major adverse cardiovascular events; PASI=Psoriasis Area and Severity Index; PGA=Physician Global Assessment.

Co-primary endpoints:
PGA 0/1 with at least a 2-point improvement, and PASI 75, both at Week 12[3]

- **After 2 doses**, by Week 12, 58% (reSURFACE 1) and 55% (reSURFACE 2) achieved PGA 0/1
  – vs placebo: 7% and 4% (reSURFACE 1 and reSURFACE 2, respectively)
- **After 2 doses**, by Week 12, 64% (reSURFACE 1) and 61% (reSURFACE 2) achieved PASI 75
  – vs placebo: 6% and 6% (reSURFACE 1 and reSURFACE 2, respectively)

INDICATION

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

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 Full Prescribing Information in pocket.

reSURFACE 1 (N=463) and **reSURFACE 2** (N=463) were Phase 3, double-blind, placebo-controlled trials of ILUMYA™ given at Weeks 0, 4, and every 12 weeks thereafter. Patients with moderate-to-severe plaque psoriasis who were candidates for phototherapy or systemic therapy were randomized to ILUMYA™ 100 mg or placebo.[1,3]

Learn more at ILUMYAdurability.com | Watch data highlights video

References: 1. Data on File. Sun Pharmaceutical Industries, Inc. **2.** Thaçi D, Iversen L, Pau-Charles I, et al. Long-term efficacy and safety of tildrakizumab in patients with moderate-to-severe psoriasis who were responders at week 28: pooled analysis through 3 years (148 weeks) from reSURFACE 1 and reSURFACE 2 phase 3 trials. Paper presented at: 27th Congress of the European Academy of Dermatology and Venereology (EADV); September 12-16, 2018; Paris, France. **3.** ILUMYA™ [package insert]. Princeton, NJ: Sun Pharmaceutical Industries, Inc.

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