



MEDLAW

## PART 1 Avoiding Liability in Telemedicine: Licensure & Coverage

Telemedicine has exploded in scope with the COVID-19 pandemic and will leave a lasting imprint on how medicine is practiced, so it is essential for physicians to understand its basic principles and the specific rules that govern it during the pandemic.

Normally, a patient's residence does not matter, because you see them in the state where you are licensed. However, when you as, for example, a doctor in Manhattan have a video visit with your patient at home just across the river in New Jersey, you are reaching into another state to practice and so your licensure status becomes of interest to that state. As a result of the COVID-19 crisis, states have extended licensure waivers. If you will be practicing telehealth with patients from states where you do not have a license, search [fsmb.org](https://fsmb.org) for "states waiving licensure requirements" to make sure that is permissible.

Bear in mind that these modifications are related to the current pandemic. Do not assume that a waiver will continue past the end of the crisis, and make sure you meet all requirements that may re-establish if you want to continue to offer remote visits to your out-of-state patients, or you could face charges of practicing without a license.

The advent of the pandemic originally provoked a retreat by insurers, many of whom wanted to exclude COVID-related issues, but that was essentially a brief reaction, and virtual care coverage is now an expanding and competitive market. However, again, beware that while these changes are significantly the result of carriers seeing an expanding opportunity even after the pandemic ends, they are currently backed up by laws that offer considerable immunity from suits for those involved in COVID-19 care. That rates may rise later when such immunization is lifted should be assumed.

If you are getting coverage to do telemedicine, remember that it is not just about malpractice. You will need adequate coverage for technical issues and for privacy breaches. If you have free coverage of some \$50,000 for cyber issues on your current policy, make sure to increase it to at least \$1 million, because any breach can be costly and telemedicine is inherently more risky being entirely in the vulnerable electronic realm.

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



## Top Predictors of NCB in Psoriasis



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Research indicates that patients with non-calcified coronary burden (NCB), particularly those with psoriasis, are at an increased risk of acute coronary syndrome, stroke, and cardiovascular mortality at a younger age. "NCB is composed of predominantly lipid-rich plaque—which patients with psoriasis have higher levels of when compared with those without the condition—that is less stable than other plaques and more prone to rupture," explains Nehal N. Mehta, MD, MSCE. "Thus, these patients have an increased risk of myocardial infarction." For a study published in the *Journal of the American Academy of Dermatology*, Dr. Mehta and colleagues sought to determine the main predictors of NCB to assist physicians in identifying it and providing interventions that could control or minimize risk factors.

### Understanding NCB Predictors

The study team developed a machine learning algorithm using more than 250 patient records from 2013-2018. The algorithm had 92 phenotypic variables measured at baseline that were later condensed to 62 variables. To determine NCB measurements, all participants received coronary computed tomography angiography (CCTA). CCTA provided the team with information on patients' lumen stenosis, arterial remodeling, and plaque subcomponents, including total, non-calcified, and calcified coronary artery burden. The researchers also conducted linear and logistic regression between NCB and the predictor variables, along with dichotomizing NCB by median NCB value for predictor variables with binary outputs.

At baseline, the majority of participants were middle-aged men, with low cardiovascular risk

by Framingham risk score, and with mild-to-moderate psoriasis. The top 20 predictors were identified using the random forest algorithm (Table). "Top predictors of NCB in psoriasis patients were markers related to obesity, dyslipidemia, and inflammation, demonstrating that these are potentially important comorbidities to treat in patients with psoriasis," emphasizes Dr. Mehta. The algorithm indicates numerically the importance of each predictor in predicting NCB, with a highest possible score of 1.0. Predictors were confirmed by unadjusted linear regression models.

Dr. Mehta stresses the importance of not only treating the inflammatory skin condition but also treating comorbidities such as obesity, dyslipidemia, and inflammation. "There is increasing evidence that treating the underlying psoriasis may improve the patient's cardiovascular disease profile in such patients, and the results of this study are in line with this hypothesis," Dr. Mehta adds.

### Looking Forward

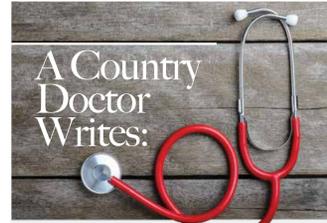
The study authors acknowledge the need for future studies to confirm their findings and reduce the risks of cardiovascular complications in patients with psoriasis. "Incorporating longitudinal data would provide additional insight into how changes in these top predictors modulate NCB," explains Dr. Mehta. "Furthermore, incorporating the incidence of actual cardiovascular events will also help augment models for risk stratification. Research in these areas would help us better understand how modulation of NCB corresponds to clinical events in this population and would provide deeper insight into how clinicians can risk stratify patients with psoriasis in order to augment clinical care. With a better understanding of risk stratification in this patient population, we will be able to provide more individualized care and appropriate treatment strategies to reduce underlying cardiovascular disease risk." ■

### Table Event Rates & Hazard Ratios

The table below depicts the event rate per 1,000 person-years and hazard ratios (HRs) for children with and without psoriasis.

Variable (n = 263)	Importance (1.0)
BMI	0.66
Visceral adiposity	0.64
Total adiposity	0.41
Apolipoprotein A1	0.22
High-density lipoprotein	0.19
Erythrocyte sedimentation rate	0.17
Subcutaneous adiposity	0.15
Small low-density lipoprotein particle	0.13
Cholesterol efflux capacity	0.11
Absolute immature granulocyte count	0.11
Total cholesterol	0.10
Waist-to-hip ratio	0.09
Apolipoprotein B	0.09
Very low-density lipoprotein particle	0.06
Absolute monocyte count	0.06
High sensitivity c-reactive protein	0.06
Large very low-density lipoprotein particle	0.05
Large medium high-density lipoprotein particle	0.04
Large medium low-density lipoprotein particle	0.04
White blood cells	0.04

Source: Adapted from: Tollefson M, et al. *JAMA Dermatol*. 2018;154:286-292.



## Meaningful Us

Meaningful Use was a vision for EMRs that in many ways turned out to be a joke. Consider my list of Meaningful Us for medical professionals instead.

When electronic medical records became mandatory, federal monies were showered over the companies that make them by way of inexperienced, ill-prepared practices rushing to pick their system before the looming deadline for the subsidies.

The feds tried to impose some minimum standards for what EMRs should be able to do and for what practices needed to use them.

The collection of requirements was called meaningful use, and by many of us, nicknamed "meaningless use." Well-meaning bureaucrats with little understanding of medical practice wildly overestimated what software vendors—many of them startups—could deliver to such a well-established sector as healthcare.

For example, the feds thought these startups could produce or incorporate high-quality patient information that we could generate via the EMR, when we have all built our own repositories over many years of practice from Harvard, the Mayo Clinic, and the like or purchased expensive subscriptions like UpToDate. As I have described before, I would print the hokey EMR handouts for the meaningful use credit and throw them in the trash and give my patients the real stuff from UpToDate, for example.

I'd like to introduce an alternative set of standards, borrowing the hackneyed phrase, with a twist: **Meaningful Us for Medical Professionals:**

### Unbiased, Understanding, Unflappable, Unhurried

Like the software meaningful use items, these may be hard to attain, but especially in today's healthcare environment, they seem worthy of striving for.

**UNBIASED** Able to fairly represent alternative approaches to allow patients to make up their own mind about their care.

**UNDERSTANDING** Able to listen to patients' concerns and reflect back that you "get it" and will work to help address them.

**UNFLAPPABLE** Able to, in Osler's words, maintain equanimity in the face of the challenges of medical practice.

**UNHURRIED** Able to use time wisely, therapeutically, without frenzy, to make the most of the most valuable resource we all have.

Now, isn't that more inspiring?

## Infection-Related Hospitalization & Mortality in Patients With Psoriasis



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Although previous studies suggest that psoriasis may be independently associated with an increased risk of serious infection—that which leads to hospitalization—the research has various limitations, and thus, the relationship remains unclear, explains Zenas Yiu, PhD. In a study published in the *British Journal of Dermatology*,

Dr. Yiu and colleagues sought to determine if patients with psoriasis, when compared with those without the condition, have a higher risk of hospitalization due to any infection, respiratory infections, soft tissue and skin infections, or death due to infection.

Using data from the nationally representative UK Clinical Practice Research Datalink linked to Hospital Episode Statistics (HES) and Office for National Statistics (ONS) mortality records between January 2003 and December 2016, the researchers matched adults with psoriasis with up to six comparators on age, sex, and general practice. Hospitalization due to infection was ascertained from HES records and death from ONS mortality records. Stratified Cox proportional hazard models were estimated, with stepwise adjustment in different models for confounding factors, including BMI, smoking, alcohol intake, socioeconomic status, and comorbid conditions. Approximately 70,000 patients with psoriasis and nearly 340,000 comparators were followed for a median of about 5 years.

"People with psoriasis had a higher incidence rate of serious infection, at 20.5 per 1,000 person-years, than the comparators, at 16.1 per 1,000 person-years," says Dr. Yiu. "After adjustment, people with psoriasis had a 36% increased relative probability of developing a serious infection during follow-up compared with the general population (hazard ratio, 1.36). However, this only translated to three out of 100 more people with psoriasis developing a serious infection after 10 years of follow-up, compared with the general population."

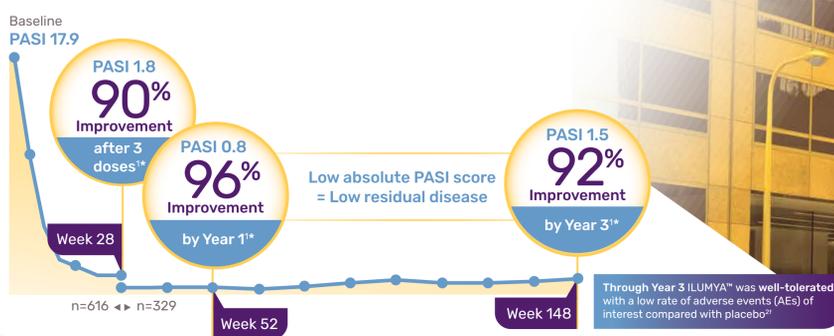
Dr. Yiu notes that while patients with psoriasis were found to have a small but increased risk of serious infection when compared with those without the condition, "because the absolute increased probability of serious infection is small, people with psoriasis should not be unduly concerned. We recommend further research to investigate whether this slight increase in the risk of infection can be explained by biological mechanisms." ■



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## HAVE CONFIDENCE IN LONG-TERM RESULTS

Median PASI Score Rapidly Reduced and Sustained Through Year 3\*



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.<sup>1,2</sup>

\*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 MACCE, deaths, injection site reactions, and drug-related hypersensitivity AEs.

\*\*Adverse event: MACCE=major adverse cardiovascular events; PASI=Psoriasis Area and Severity Index; PGA=Physician Global Assessment.

### 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.<sup>1,2</sup>

References: 1. Data on File, Sun Pharmaceutical Industries, Inc. 2. Thaçi D, Iversen L, Paus-Charles L, 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, 2016; Paris, France. 3. ILUMYA™ (package insert). Princeton, NJ: Sun Pharmaceutical Industries, Inc. ILUMYA is a trademark of Sun Pharma Global FZE. © 2020 SUN Dermatology, a division of Sun Pharmaceutical Industries, Inc. All rights reserved. PM-US-ILY-1073-07/2020