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WHAT'S NEWS

The end of meaningful use will come this year, and it will "be replaced with something better," says CMS's Andy Slavitt. **11**

Etanercept exposure in pregnancy was associated with more than twofold higher odds of major structural defects, says Christina D. Chambers, Ph.D. **14**

Pretreatment with sulfasalazine seems to prevent TNFi antibodies, but not as well as methotrexate. **18**

The first U.S. clinical practice guidelines for Sjögren's are issued for systemic treatment, oral disease, and dry eyes. **24**

Several state laws that permit privileged discussions between physicians and patients after medical errors are showing promise. **54**

WHO'S TALKING

Reminder letters

Step therapy and biologics: An easier road ahead?

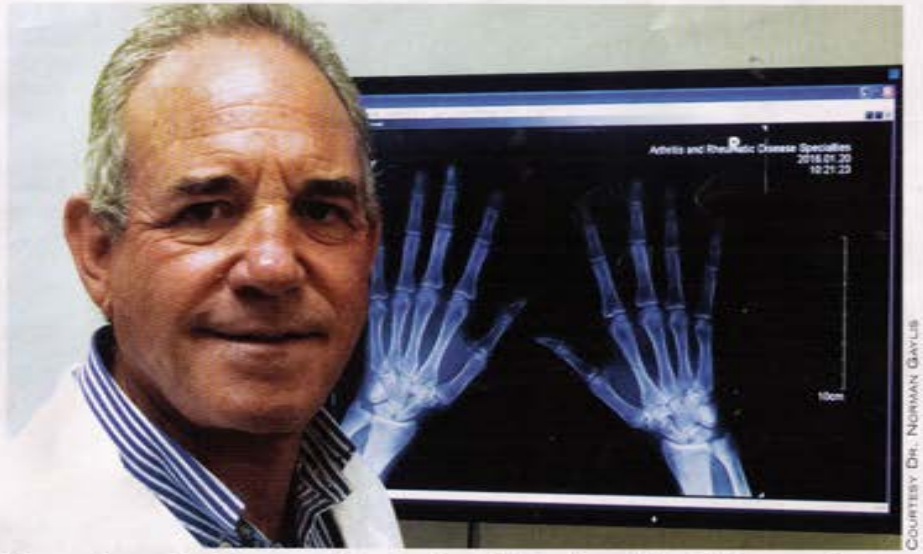
Twelve states have passed legislation on step therapy varying in focus and scope.

BY JENNIE SMITH

Laws recently passed or under consideration in state legislatures may offer some relief to physicians and patients dogged by the "step" or "fail-first" therapy protocols mandated by insurers, but until better clinical evidence is available to support treatment decisions and biosimilars reduce costs, clinicians must strategize to get patients through the step pathways as fast as possible.

Rheumatologists, gastroenterologists, and dermatologists all confront fail-first policies in their practices, particularly when prescribing the biologic agents that have been game changers in treating rheumatoid arthritis (RA), inflammatory bowel disease (IBD), and psoriasis, among other diseases.

In RA, for example, a patient might be required to fail a series of disease-modifying antirheumatic drugs (DMARDs), including methotrexate, before starting a biologic. In Crohn's disease, patients might have to first fail on steroids and immunosuppressants.



COURTESY DR. NORMAN GAYLIS

'By creating a step therapy pathway we're closing the window [of opportunity to treat these diseases] at least partially,' said rheumatologist Dr. Norman Gaylis.

Most clinicians consider cost con-

See **Step therapy** *page 2*

Integrated care recommended for PsA

Lowering hurdles for biologics

Step therapy *from page 1*

cerns fair as a basis for insurance decisions. But they can also have strong rationales for making exceptions. This may mean starting patients on a biologic early, particularly those they deem unlikely to respond to first- or second-line treatments – which may be cheaper but are not necessarily safer.

In egregious cases, a patient already stable on a biologic who has changed insurance plans may be forced to go backwards in the treatment pathway, and fail first- and second-line therapies all over again before resuming – a process unlikely to be cost-effective in the long term, and also rife with ethical concerns, say clinicians.

"Making a patient fail to get a less toxic drug sort of violates our 'do no harm' principle," Dr. Stephen B. Hanauer, medical director of the Digestive Health Center at Northwestern University, Chicago, said in an interview.

"I always say that if biologics cost a dollar, we'd be using them for everybody. If you take away the steroids and the immunosuppressants, these are very safe drugs for IBD, far safer than steroids – but steroids are cheap," Dr. Hanauer said.

As insurers' first-choice biologic drug changes frequently, and varies from plan to plan, a patient who is stable on one agent might be asked to switch to another, a phenomenon known as nonmedical switching.

And with some debilitating disease presentations, such as severe Crohn's, "being told that we have to try conventional therapies and the patient has to fail them can mean putting the patient through progression of their disease, and suffering," Dr. David T. Rubin, codirector of the Digestive Diseases Center at the University of Chicago, said in an interview. "We really struggle with this."

Dr. Joseph S. Eastern, a dermatologist practicing in Belleville, N.J., said his specialty faces similar challenges with step therapy. "Dermatologists as a group are pretty risk averse. When given the opportunity, we do an excellent job of prescribing conventional medications, ultraviolet therapy, and biologics in the most cost-efficient possible way," he said in an email.

'Making a patient fail to get a less toxic drug sort of violates our "do no harm" principle.'

DR. HANAUER

Yet "third-party payers tell us, for example, that a patient must fail methotrexate before we can use a biologic, when the whole advantage of biologic therapy for many of these patients is the avoidance of organotoxicity and other serious risks."

As a result, Dr. Eastern said, "I write a lot more vehement letters to payers about the biologics these days."

Choice vs. cost

Rheumatologists are among the clinicians most affected by fail-first and step therapy mandates, as the diseases they treat – particularly RA – are the most established indications for biologic therapies, and for which the largest number of these are approved.

Though Medicare and Medicaid allow physicians considerable leeway, private insurers often tightly circumscribe the timing and choice of biologics in RA. As insurers' first-choice biologic drug changes frequently, and varies from plan to plan, a patient who is stable on one agent might be asked to switch to another, a phenomenon known as nonmedical switching.

Insurers are seldom transparent about their reasons for establishing certain biologic drugs as their go-to agents, clinicians say, while making it difficult for physicians to prescribe others. "There's a tremendous amount

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of discounting going on that we are oblivious to as physicians. I've seen situations where drug A is the first one you have to use this month and the next month, drug C," said Dr. Norman Gaylis, a rheumatologist practicing in Aventura, Fla.

Attempting to start a patient on a nonpreferential biologic will generate paperwork and delays, Dr. Gaylis said, which can cost patients valuable time. "There's a window of opportunity to treat these diseases, and by creating a step therapy pathway we're closing the window at least partially."

"As an example, rituximab in most payer plans is not tiered as a first-line biologic treatment option despite the fact that there are frequent scenarios where the clinical and serological presentation of a patient would suggest it to be preferable as a first-line treatment choice over an anti-TNF [tumor necrosis factor]," Dr. Gaylis said.

Model legislation for limiting step therapy has three basic objectives: 'We want a clear set of clinical guidelines, a quick review process, and overrides that allow for exceptions.'

"There is no room for clinical decision making based upon the unique presentation of each different patient when choosing the best treatment option," he said.

Rheumatologists often become overwhelmed with authorization paperwork, Dr. Gaylis said, and for those who must move into the biologic realm, the vast majority will succeed on the first anti-TNF agent prescribed. And there is little science to establish that one TNF inhibitor is superior – only that patients can sometimes succeed with one and fail another.

"As far as which biologic to initiate, my personal opinion is I don't care, and I tell the patients that I don't mind if the insurer picks out of this category because I'm flipping a coin as well," she said.

'When I say I have tried this patient on maximal tolerable doses of all these DMARDs, they ought to believe me.'

DR. KOLBA

Step mandates become objectionable, Dr. Kolba said, when they are purportedly based in science that doesn't exist, or when they seem to exist only to wear down the provider.

"With private insurance, not only do they have the drug of the year, they're going to make me battle for every single prescription. When I say I have tried this patient on maximal tolerable doses of all these DMARDs, they ought to believe me. Yet I get six-page forms back saying, 'Give me the start and stop dates of all the drugs you've used.'"

States constrain fail first

For many specialists treating patients with biologics, some of these hurdles are already getting lowered.

Moreover, he said, "we'd seen protocols requiring five or more steps, and for each step you have to try it at least 90 days." For a patient with rheumatic or autoimmune disease, "getting through something like that can just be devastating."

In 2011, Connecticut, Mississippi, and Arkansas became the first states to pass legislation limiting some aspect of step therapy. Since then, nine additional states have passed legislation varying in focus and scope.

In Kentucky, for example, patients cannot be forced by their insurer to remain on an ineffective therapy for more than 30 days, and insurers must respond to physician requests for an override within 2 days. Mississippi allows physicians to override insurer decisions with proof of clinical evidence. In California, legislation passed last year aims to reduce bureaucracy and speed up response to physician requests for overrides.

Mr. Stone and Mr. Okazaki are working in a coalition with other dermatology, rheumatology, and GI groups to push bills in seven more states, including New York, North Carolina, and Ohio.

While all the bills differ in what they attempt to limit, the model legislation has three basic objectives, Mr. Okazaki said. "We want a clear set of clinical guidelines, a quick review process, and overrides that allow for exceptions in cases where patients

'We're all looking for that magic

insurer in favor of a biologic drug is insufficient clinical evidence.

With IBD, Dr. Rubin said, "we need more longitudinal understanding" and better prognostic indicators "in order to justify spending the extra money or going to one of these therapies."

Dr. Hanauer said one of the limitations he faces in practice is insufficient clinical evidence for biologics early in the treatment pathway for IBD.

'We need more longitudinal understanding' and better prognostic indicators to justify biologics.

DR. RUBIN

RA "is much more common than Crohn's disease is. In trials, it's much easier to recruit hundreds of patients [for an RA trial], while with Crohn's it's very hard to enroll more than a couple a year at most sites," he said. "And as you move earlier in the treatment pathway that becomes somewhat more difficult as well."

His solution for now, he said, is to follow established step pathways in an accelerated way, for "a rapid transition toward highly effective therapies" without having to face extensive pushback from insurers.

"The idea is to initiate immunosuppressants for any patients with sufficient disease activity to justify steroids," Dr. Hanauer said. "Their steroids are then tapered, and while on immunosuppressants, patients are in a perfect setup to get combination

sentation of a patient would suggest it to be preferable as a first-line treatment choice over an anti-TNF [tumor necrosis factor]," Dr. Gaylis said.

Model legislation for limiting step therapy has three basic objectives: 'We want a clear set of clinical guidelines, a quick review process, and overrides that allow for exceptions.'

"There is no room for clinical decision making based upon the unique presentation of each different patient when choosing the best treatment option," he said.

Rheumatologists often become overwhelmed with authorization paperwork, "and still in many instances end up with a denial of their request."

Dr. Karen Kolba, a rheumatologist in private practice in Santa Maria, Calif., said that she agreed in principle with the way step therapy protocols have been established, and that some of the frustration with step therapy amounts to a tendency among specialist clinicians to bristle at being told what to do.

"Physicians hate protocol," Dr. Kolba said. "But comparing one protocol to another is the only way we are going to make advances." It took the rheumatology community about 30 years to come to terms with the use of methotrexate in RA, she noted, and the stepped approach grew naturally from the treatment of methotrexate failures with biologic agents when these first emerged in the late 1990s.

A majority of RA patients started on a stepped approach using DMARDs will respond, Dr. Kolba category because I'm flipping a coin as well," she said.

Step mandates become objectionable, Dr. Kolba said, when they are purportedly based in science that doesn't exist, or when they seem to exist only to wear down the provider.

"With private insurance, not only do they have the drug of the year, they're going to make me battle for every single prescription. When I say I have tried this patient on maximal tolerable doses of all these DMARDs, they ought to believe me. Yet I get six-page forms back saying, 'Give me the start and stop dates of all the drugs you've used.'"

States constrain fail first

For many specialists treating patients with biologics, some of these hurdles are already getting lowered.

Concerns about physician choice, a lack of transparency in insurer decision making, and the ethics of forcing patients to fail have led advocacy groups to press hard in recent years for legislation limiting step therapy – with successes in a dozen states.

While the state legislation is not disease or drug specific, it has important implications for clinicians treating with biologics. "Step therapy in its genesis was a good idea – it's OK to try to reduce costs in the health care system," said Patrick Stone, state government relations manager at the National Psoriasis Foundation in Annapolis, Md., a group that works extensively on step therapy issues. "But when these protocols were first crafted, medications like biologics weren't in use."

Jeff Okazaki, associate director of the Coalition of State Rheumatology Organizations, a group based in Schaumberg, Ill., said lawmakers are starting to accept that in terms of cost override within 2 days. Mississippi allows physicians to override insurer decisions with proof of clinical evidence. In California, legislation passed last year aims to reduce bureaucracy and speed up response to physician requests for overrides.

Mr. Stone and Mr. Okazaki are working in a coalition with other dermatology, rheumatology, and GI groups to push bills in seven more states, including New York, North Carolina, and Ohio.

While all the bills differ in what they attempt to limit, the model legislation has three basic objectives, Mr. Okazaki said. "We want a clear set of clinical guidelines, a quick review process, and overrides that allow for exceptions in cases where patients shouldn't have to go through step therapy."

'We're all looking for that magic biologic marker to tell me which drug to use, because God knows if I had a blood test that said "this is the drug," I would go to the mat with the insurer.'

Clinical strategies and research gaps

New legislation undoubtedly will help providers and patients get access to their choice of treatment agents. But so long as biologics are expensive – and it will be a while before the first biosimilar drugs, which will have efficacy and safety similar to their reference biologics, reduce prices in any meaningful way – step therapy will likely remain the norm.

One of the key difficulties providers face when pushing back on an IBD.

RA "is much more common than Crohn's disease is. In trials, it's much easier to recruit hundreds of patients [for an RA trial], while with Crohn's it's very hard to enroll more than a couple a year at most sites," he said. "And as you move earlier in the treatment pathway that becomes somewhat more difficult as well."

His solution for now, he said, is to follow established step pathways in an accelerated way, for "a rapid transition toward highly effective therapies" without having to face extensive pushback from insurers.

"The idea is to initiate immunosuppressants for any patients with sufficient disease activity to justify steroids," Dr. Hanauer said. "Their steroids are then tapered, and while on immunosuppressants, patients are in a perfect setup to get combination therapy with an immunosuppressive and a biologic – and that's a 2- to 3-month transition, not 2-3 years."

Dr. Kolba said that despite the wide array of options for treating RA, the specialty suffers from a dearth of understanding as to why some patients fail drugs while others succeed, even within the same drug class.

Rheumatologists' prescribing choices would be highly influenced by better biomarkers, were they to become available, she said. And they'd have far better arguments when confronted with payer pushback.

"We're all looking for that magic biologic marker to tell me which drug to use," Dr. Kolba said, "because God knows if I had a blood test that said 'this is the drug,' I would go to the mat with the insurer."

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