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Clinical Update

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INSIDE THIS ISSUE

LETTER FROM THE CMO

Making the connections

Dr. Andrew Hertler
CHIEF MEDICAL OFFICER
EVOLENT

THE NEW CLINICAL UPDATE WILL PROVIDE INSIGHTS ACROSS MULTIPLE SPECIALTIES AND THE LINKS BETWEEN THEM.

For members with complex health conditions, better outcomes rarely come down to one provider, one decision or one choice of therapy. They result from a host of providers working in synchrony — and with the patient — to achieve a care plan that follows the evidence and respects the patient's values and wishes.

Yet, our health care system can sometimes seem as if it was set up to prevent this kind of connectedness. Patient-related information is scattered across different health IT systems that don't "talk" with one another. Decisions on testing and treatment are often made in isolation. Patients struggle to understand the big picture of their care in a fragmented system.

Still, I don't have to look far to find causes for optimism. On the national level, I'm encouraged by the interoperability provisions in CMS's long-awaited prior authorization rule. The more easily providers and plans can get a 360-degree picture of a member's health, past utilization and more, the better equipped we will be to manage that entire journey — and the better informed all members will be about the prior authorization process. While some may quibble with technical aspects of these requirements, the new rule will hopefully remove one of the barriers to better outcomes. With information free to move between different systems, the stage will be set for a new wave of innovation that we're just starting to imagine. See the article on page 4 for insights.

Here at Evolent, we're in a position to connect care across specialties and primary care in ways we've never done before. Last year, we brought together our expertise in three of the top specialty categories by spend — oncology, cardiology and musculoskeletal care — plus other high-volume services, such as radiology, genetic testing and physical medicine, under one brand. Together with our advance care planning capabilities, they give us the opportunity to better manage quality and cost across specialties, providers and settings throughout the care journey.

Our efforts to bundle authorizations (page 6), though still in their early stages, hint at the potential of our integrated approach. **We're rolling out new capabilities later this year that will enable us to approve months' worth of chemotherapy treatments, supportive medications and imaging services in one authorization.** Beyond this, we can envision more global authorizations that facilitate many of the services that patients with cancer need — such as genetic testing to inform treatment approaches. Not only would these ensure that an entire treatment plan follows the latest evidence, but it would relieve providers and patients from the paperwork and delays causes by traditional prior authorization practices, where each new service is reviewed separately.

With this new multi-specialty approach, it's fitting that we also change the approach of this newsletter. Until now, Clinical Update has focused on issues and innovations affecting oncology. Starting with this issue, we'll provide insights and highlight innovations across a variety of specialties, and on issues that affect specialty care utilization management in general. Whenever possible, we'll showcase areas where we're working across different areas to elevate the entire care experience.

It's not only about reflecting the new Evolent, but representing the way that members and patients experience their care — not as a single visit but as a journey.

I hope you enjoy the new Clinical Update.

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SPOTLIGHT

Imagining our interoperable future

CMS'S NEW INTEROPERABILITY AND PRIOR AUTHORIZATION REQUIREMENTS ARE STILL YEARS FROM TAKING EFFECT, BUT THEY'RE ALREADY PROMPTING US TO PONDER THE POTENTIAL IMPACTS.

Early this year, the Centers for Medicare and Medicaid Services (CMS) published a long-awaited rule creating new requirements around prior authorization and interoperability.

Aside from requiring affected plans to make determinations within seven days for routine requests and three days for urgent requests (not including for drugs), the rule seeks to improve data exchange between plans, providers and patients. By helping data flow more freely, CMS aims not only to bring greater transparency and efficiency to the prior authorization process but also to improve overall care coordination.

While most of the requirements do not take effect until the start of 2027, it's not too early to think about how things might change in a more interoperable world. How might the CMS rule itself change health care, and might it be leveraged to further enhance the experiences of individuals, providers and clients?

Time will tell how this unfolds, but here are several areas of potential impact:

SHORTENING THE PRIOR AUTH "SCAVENGER HUNT"

Many of the hours that providers spend submitting prior authorization requests involve transposing information from the medical record into a portal, tracking down and uploading documents (sometimes from outside providers), and scouring the record to answer questions to satisfy medical criteria. The new rule conjures a world in which much of that required information flows more effortlessly (yet securely) between health IT systems, automatically populating requests with relevant information. In a world of interoperable data, artificial intelligence tools could scour the record in search of answers to medical necessity criteria. It's possible that, in the future, systems could cull information directly from the electronic health record and grant prior authorization, reducing the dependence on portals.

FEWER, BETTER PEER-TO-PEER CALLS

Ideally, peer-to-peer calls should assist decision-making in complex cases or provide an opportunity to educate providers on the latest evidence. Yet too often, they're prompted by lack of information. In fact, about half of the submissions that Evolent reviews which do not receive automatic authorization are due to missing information. If leveraged wisely, interoperable data might reduce the odds of missing information and save more time for everyone — providers, clinical reviewers and plans.

MORE INFORMED AND ENGAGED MEMBERS

To many members, prior authorization occurs beneath the surface. Many don't see it or know it exists, but when they do, what they glimpse is just like the tip of an iceberg. The interoperability rule envisions a world where members have greater clarity into the process and can easily access information about prior authorization decisions affecting them. This aspect of the rule wouldn't only increase transparency around payers' decisions but might also prompt more productive discussions between members and providers — for example, about the different options for their plan of care or the need to try conservative care before seeking surgery.

CONTINUITY OF MEMBER CARE REGARDLESS OF COVERAGE

The new CMS rule also contains provisions for plans to create and maintain application programming interfaces for data-sharing with one another. This would not only provide a more complete picture of members' health and past utilization, but it could also smooth out the sometimes inefficient transitions when members change plans in the middle of a course of treatment. If someone has been receiving chemotherapy for the final 90 days of the year and needs to continue on it for 60 more days after they change coverage, that should be a more seamless process than it often is today.

The new CMS rules have set a baseline for sharing data around member care and prior authorizations. It's a major change for patients, providers and plans. But in many respects, it may just be creating the conditions for innovations that we're just beginning to grasp.

API REQUIREMENTS

With its prior authorization and interoperability rule, CMS will require payers to adopt and maintain several application programming interfaces (APIs) by January 1, 2027.

- **Patient Access API** to share information with patients about prior authorizations of services requested on their behalf (except for drugs).
- **Provider Access API** to share patient data with in-network providers with whom the patient has a treatment relationship, in order to support care coordination and the move toward value-based care.
- **Payer-to-Payer API** to make available data about certain claims, encounters and prior-authorization data (excluding drugs) with other payers.
- **Prior Authorization API** which lists covered services, items and documentation requirements, and supports prior authorization requests and responses. The APIs must also communicate details about approvals, denials and requests for information.

Bundled authorization program aims to ease provider burden

APPROVING UP TO A YEAR'S WORTH OF AUTHORIZATIONS FOR CANCER TREATMENT AND RADIOLOGY STUDIES IS A STEP TOWARD A MORE HOLISTIC APPROACH.

A well-designed cancer care plan often goes well beyond the selection of the right therapies. It may demand the coordination of multiple services — genetic testing to identify the best treatment options, imaging studies before and during treatment, and more.

Yet, traditional utilization management typically approaches each instance of these services in isolation, rather than part of a holistic plan, and often with different companies providing clinical oversight on different specialties. Each new request requires additional work by the provider and introduces new risks for delays and errors.

Evolent is working to create a new model. Later this year, we will begin piloting a new bundled authorization capability, enabling providers to receive up-front authorization for imaging studies for up to a year, in tandem with courses of anticancer therapy. Based on conservative estimates, these bundled authorizations will reduce the number of provider requests by more than 80 percent, while ensuring that patients receive high-value treatments without delay.

Bundles are suited to many cancer cases because treatments and imaging studies follow a predictable pattern — studies are used at first to stage the cancer, and then afterwards at set intervals to measure the patient's response to treatments.

"We're building a process that goes beyond traditional UM to reflect the reality of how cancer care is delivered," said Evolent Medical Director of Oncology Imaging and Genetic Testing Sadie Dobrozsi, a pediatric oncologist who is spearheading the bundling effort. "Rather than treat each individual service as

a new request, as if they were a patient who needs an MRI after a ski accident, we can review and approve many services across an episode of care."

Dobrozsi has developed 64 condition-based guidelines for high-tech imaging in cancer care. Each imaging bundle comes with diagnosis-specific studies and timing that are aligned to Evolent's high value clinical oncology pathways. Providers will receive auto-approval for bundled regimens that are on pathway, but they can also seek to customize those bundles based on the patient case.

> "We're building a process that goes beyond traditional UM to reflect the reality of how cancer care is delivered."

Dr. Sadie Dobrozsi
MEDICAL DIRECTOR OF ONCOLOGY IMAGING AND GENETIC TESTING
EVOLENT

Future plans will allow providers seeking bundled authorizations to add genetic testing that may be appropriate in the patient's case. When anticancer drugs pose a potentially harmful effect on the heart or cardiovascular system, they will also be prompted to seek periodic cardiovascular studies. Eventually, authorization for these services and others could be part of a more global authorization system, enabling providers to get approval for large stretches of the patient care roadmap, where appropriate.

5 → 1

reduction in average number of requests per episode

UP TO

12

months of imaging authorizations in one approved bundle

64

condition-based guidelines for high-tech imaging (MRI/CT/PET)

LEARN MORE ABOUT BUNDLED AUTHORIZATIONS

Interested in learning more about our bundled authorization approach and how your plan could benefit? Email **connect@evolent.com** to schedule a briefing with one of our clinical experts.

LOW-VALUE CARE

Preventing inappropriate epidural steroid injections

EVOLENT'S INTERVENTIONAL PAIN MANAGEMENT TEAM SEEKS TO ENSURE PATIENT SAFETY AS WELL AS APPROPRIATE PAIN RELIEF FOR MEMBERS EXPERIENCING LOW BACK PAIN.

Low back pain takes an enormous toll on the health of Americans, ranking first among diseases and injuries in years lost to disability.[1] It also exacts a massive financial toll: low back and neck pain together account for highest amount of health care spending of any condition.[2]

Epidural injections are commonly used in the diagnosis and treatment of low back pain, such as from ruptured discs. Yet while these injections often bring relief and improve function, their potential benefits should be weighed against potential side effects, including weakened immune systems and decreased bone density.

CHANGING GUIDELINES VS. STUBBORN HABITS

For years, it was standard practice for pain management specialists to initiate treatment through a series of three epidural steroid injections, separated by a week or two. Pain relief would typically be assessed only at the end of those injections.

That approach was upended more than a decade ago with guidelines from the American Society of Interventional Pain Physicians that sought to balance the need for relief against the risks. For example, the guidelines recommend that patients get a second injection no sooner than 2 weeks after

[1] Lancet. 2018 Nov 10;392(10159):1859-1922. doi: 10.1016/S0140-6736(18)32335-3.
[2] JAMA. 2020;323(9):863–884. doi:10.1001/jama.2020.0734

the initial injection — and preferably after 4 or 6 weeks — and only after a reevaluation. The provider may decide to change their technique or the location of the injection based on that visit.

Yet, while many interventional pain management specialists quickly adopted the guidelines, there are other providers who continue to follow the outdated practice of back-to-back-to-back injections.

OUR APPROACH

Evolent's Interventional Pain Management (IPM) team, part of our Musculoskeletal Care Solution, works to ensure patient safety and efficacy of these injections. By identifying providers with higher rates of potentially inappropriate requests, and then educating them via peer-to-peer reviews, we aim to change ordering habits in the long run.

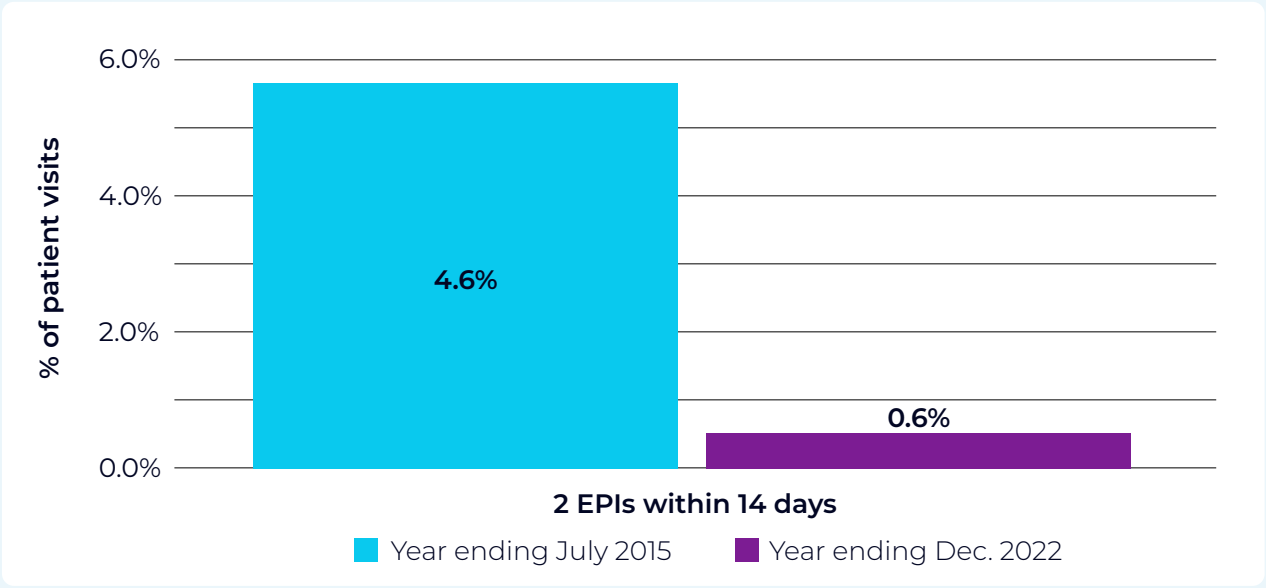
"One of the main things that we focus on in our peer-to-peers is understanding the adverse effects of steroid injections and spacing those out appropriately to reduce that exposure and risk to the patient," says Stephanie Thompson, Evolent's medical director of interventional pain management and physical medicine. Evolent peer reviewers — all of whom are board-certified interventional pain management specialists — also ensure steroids are appropriate in the first place. They may educate providers on the need for patients to first attempt physical therapy or other conservative steps before receiving the injection.

RESULTS

By working with providers and applying the latest guidelines, Evolent's interventional pain management program has steadily driven down use of inappropriate epidural steroid injections.

REDUCING INAPPROPRIATE EPIDURAL STEROID INJECTIONS

Guidelines call for at least 14 days between epidural injections (EPIs) during the initial "therapeutic" phase. At one commercial health plan, Evolent has worked with providers to achieve a reduction of 87%.



A potential new paradigm for solid tumor treatment

LIFILEUCEL SHOWS PROMISE FOR METASTATIC MELANOMA TREATMENT, BUT QUESTIONS ABOUT TOXICITY REMAIN.

In mid-February, the FDA granted accelerated approval to lifileucel (Amtagvi) for the subsequent therapy of metastatic melanoma. It marked the first indication in a long-awaited class of treatments, called tumor infiltrating lymphocyte (TIL) therapy, that involves harvesting the patient's own cancer-fighting T-cells, growing billions more in the lab, and then infusing them back into the bloodstream.

Given that most cancers are solid tumors, TIL therapies could eventually cover a wide range of indications. In fact, the U.S. government's clinical trials database lists more than 300 active trials for TILs, with roughly half in phase 2 or 3 today. The therapy has already shown promising tumor responses in people with lung, ovarian, and head and neck cancers.[1]

LIFILEUCEL: ASSESSING CLINICAL TRIAL DATA

So, what does the lifileucel clinical trial data show? While it offers hope for a group of melanoma patients who have exhausted most other treatment options, it's important to weigh that against the risks of treatment, and other considerations.

- **Efficacy.** Nearly a third of the 73 patients in the analysis (31.5%) experienced tumor reductions. Of those who responded, 40% had no progression of their cancer for a year

1 https://www.cancer.gov/news-events/cancer-currents-blog/2024/fda-amtagvi-til-therapy-melanoma.

after infusion, and some patients haved maintained the response for at least 45 months. Median overall survival was nearly 14 months. By comparison, overall survival for patients on chemotherapy or best supportive care — common paths for this population — is about half that duration.

- **Toxicity.** Significant numbers of patients experienced serious treatment-related adverse events (see below). Treatment-related mortality was 7.5%, including two deaths resulting from disease progression and four from adverse events within 30 days after lifileucel administration. These adverse events were likely influenced by other steps in the TIL treatment process, which involves giving the patient a chemotherapy regimen to prepare the body for the infusion, and giving patients other therapies post-infusion to stimulate the TILs.

Cost		$515,000
Efficacy	Objective response rate[2]	31.5%
	Median overall survival	13.9 months
	Duration of response	Up to 45+ months
Grade 3 or 4 Adverse events	Thrombocytopenia	78%
	Anemia	58%
	Febrile neutropenia	47%
	Treatment related mortality	7.5%

These risks should be taken seriously given the trial's highly selected patient population — a group of healthier patients (ECOG performance status 0/1) who should be more likely to tolerate the treatment.

EVOLENT'S RECOMMENDATION TO HEALTH PLANS

Evolent oncology experts recommend that health plans add lifileucel to their formularies. We plan to review the treatment for pathway inclusion in an upcoming meeting and will continue to follow this class of drugs.

LEARN MORE ABOUT LIFILEUCEL

Email **medical_pharmacyteam@evolent.com** to request a copy of a New Drug Review, in which our oncology experts delve into the data surrounding this treatment.

[2] Reduction in size of tumors

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Specializing in Connected Care.™

Evolent partners with health plans and providers to achieve better outcomes for people with complex health conditions. Working across multiple medical specialties and primary care, we seek to ensure that care plans align with clinical evidence, respect members' goals and preferences, and connect seamlessly across providers and settings. Evolent serves a national base of leading payers, including managed Medicaid, Medicare Advantage and commercial health plans. Through a comprehensive suite of resources — such as high-value clinical pathways, electronic decision support and value-based payment models — we create an ecosystem that helps providers deliver better, more affordable care to their patients. Tens of millions of Americans have access to our clinical expertise through their plans. Learn more about Evolent **evolent.com**

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