

The Business of Gastroenterology

Quarterly Newsletter | Q2 2021

Biosimilars on the Move

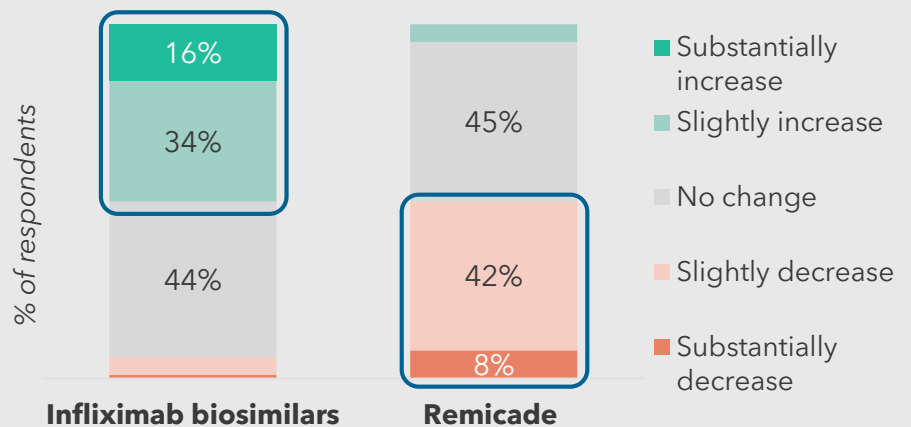
In January 2021, United Health and Cigna adjusted the formulary status for Janssen's Remicade in favor of certain infliximab biosimilars (including Pfizer's Inflectra and Amgen's Avsola), resulting in a disadvantage for the name brand.

In this quarter's issue included in **Special Topix™: The Business of Gastroenterology**, recently collected data reveals changes in Remicade versus infliximab biosimilar prescribing. Key notes from our interview with Gastrologix principal, Chris Metz, and his perspective on the current treatment landscape are also highlighted.

According to 93 gastroenterologists surveyed in July-August 2021, roughly one-half estimate their **prescribing of infliximab biosimilars increased** when compared to the period prior to COVID-19.

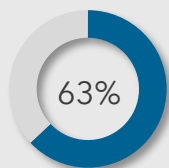
With the increase in infliximab biosimilar prescribing, one-half of gastroenterologists estimate their prescribing of Remicade decreased compared to before the pandemic.

Change of Overall Use: Infliximab Biosimilars vs Remicade

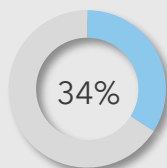


Leading Reasons for Infusion Volume Decrease in Remicade

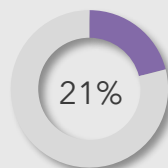
% of respondents



Decreased insurance coverage for Remicade



Improved insurance coverage for other agents



Concerns about COVID-19 transmission in facility

When gastroenterologists were asked what specifically led to a decline in Remicade infusion, "**decreased insurance coverage for Remicade**" was the number one reason.

Additionally, "improved insurance coverage for Remicade competitors" was the second most common reason for the decrease in Remicade infusion.

Q2 Transactions

April

- Gastroenterology Health Partners joins One GI
- Gastroenterology Associates of Wyoming joins Gastro Care Partners
- Gastrointestinal and Liver Specialists of Tidewater joins Capital Digestive Care

May

- East Atlanta Gastroenterology Associates to United Digestive

June

- Gastroenterology & Hepatology Associates joins Gastro Health
- Hong Gastroenterology joins Gastro Health
- Colorado Gastroenterology joins GI Alliance

Gastro Health Experiences Second Turn with Sale to OMERS Private Equity

In May 2021, GastroHealth was sold to OMERS private equity for an estimated \$960M by Audax private equity. Under Audax's sponsorship, GastroHealth had **grown from 53 doctors to over 250 doctors** and operates in 6 States (FL, AL, OH, WA, MD & VA). Since the initial investment in 2016, GastroHealth has implemented a new centralized EMR and billing software, centralized purchasing, contracts and developed specialty pharmacy and infusion services.

The latest transaction is further proof that pharma stakeholders must engage the scaled MSO customer or risk losing market share to competitors that address the MSO's needs.



Meet the Expert: Chris Metz, Principal Gastrologix

Q. Tell me about Gastrologix.

Gastrologix is a niche, single specialty GPO, servicing independent GI practices around the country. But we really consider us more of a business development organization working on behalf of the independent practices who are members of the GPO. In this regard, we accomplish our mission, if you will, of helping GI practices be more efficient, make more money, and operate better.

Q. What are the implications of the UnitedHealth formulary change that incentivizes for Inflectra and Avsola while de-emphasizing Remicade?

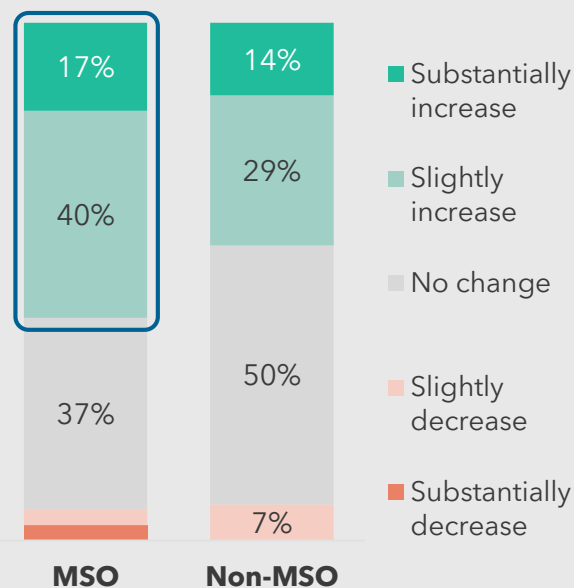
It becomes a payer mix issue for a practice. So, if my payer mix has 25 percent United, that's going to impact the change in the rebate program. Because of the payer mix, practices have to use more than a certain percentage of the biosimilars than Remicade. Then, once they hit that point, it's an all-or-nothing rebate dynamic. It's not as if the rebate goes down [in] a rational type of way. Once you go below that threshold, the rebate from J&J goes away. In order to get the maximum rebate for Inflectra, you are then incentivized to use as much Inflectra as possible to get over their threshold. And so, if there's a payer mandate, it's too much work over time for a practice to keep fighting that fight.

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In the graph below, MSO gastroenterologists were even more likely to increase infliximab biosimilar prescribing than their non-MSO counterparts.

Change of Overall Use of Infliximab Biosimilars: MSOs vs. Non-MSOs

% of respondents



Meet the Expert: Chris Metz, Principal Gastrologix (continued)

Q. We had the second oral therapy get approved for ulcerative colitis. Does this mean that practices are going to start getting more involved in specialty pharmacy?

We've been advocating for groups to build their own in-office pharmacy, to develop it and to create the dispensing capability, even if you're just breaking even. Do that now so you have the infrastructure in place as your infusion patients transition to self-injectables and orals. Your present-day infusion patients, they're already transitioning to self-injectables. They're going to, over time, translate into oral therapy. And if you don't have in-office dispensing or pharmacy capability, you've lost those patients from a financial perspective. So, we're advocating these services as a financial hedge.

We want to start talking to the pharmaceutical companies and get them to be advocates of physicians having this capability in their office. That's going to be better for patient adherence to the orals. We want to work with pharmaceutical companies, develop the protocols and figure out how to go at risk so that the physicians are in charge of those protocols. This way, you get rid of the step therapy and get the right drug to the right patient as soon as possible.

The graphs below show that a majority of gastroenterologists do not dispense IBD medications from their office and a majority of those who don't dispense, do not have plans to change that situation anytime soon.

Percent of Gastroenterologists Who **DO NOT** Dispense Prepackaged IBD Medications Directly from Office



Percent of Gastroenterologists Who Have **NO** Plans of Incorporating Direct Dispensing Into Their Practice



The payers, manufacturers and PBMs like the present situation because they are sharing in the current convoluted rebate structure. They think that's a great thing, but I want to try to change the dynamic where the payers think about developing physician-led and physician-centric approaches to that. Let the physicians have some financial upside in that process because then the protocol is going to be more effective. Your adherence is going to go up and your overall spend is going to go down because the patients are going to do better over time.

And so, my opinion is that the payers right now, take the short-sighted view. As a result, they play all the games with the PBMs and the manufacturers, and think they're doing fine with that. I'm sure they are, but really, I think the long-term play is to get the physicians to be more involved, especially in these patients where it's a chronic disease and a very costly disease.

Q. Right. Because at some point, there's going to be a sort of reckoning, if you will, in terms of how well these patients are doing under this old system, where potentially, the newer system allows for more closer monitoring and making sure that the patient is doing well, staying on the meds, and so on. And that's a key component for all of this.

And I think the more you have the practice - whether it's the doctor, the nurse, or the appropriate staff member - in charge of that program and maintaining that communication, the better. It's better that the interaction comes from the practice than from a payer or a third-party entity that's trying to stay in touch with the patient.

Full interview transcript available per request.

SPECIAL TOPIX

Service Overview

Special Topix™: The Business of Gastroenterology (US) is an independent service that will help pharma stakeholders understand the implications of this evolving landscape, as it will affect strategic decisions around field force deployment, contracting, specialty pharmacy engagement, clinical trial scale, and support services that will be expected from pharmaceutical partners.



Fraser Healthcare, a growth strategy consultancy specializing in private equity funded MSO transactions, and **Spherix Global Insights** are partnering to provide an actionable overview for pharma stakeholders in the evolving market to be able to react and plan for future expansion of this model.

Research Methodology

Qualitative interviews

n=15 executives at MSOs, physicians who recently joined, influencers, specialty pharmacy representatives




Quantitative survey

Survey to practicing gastroenterologists (n=121) including:
n=45 affiliated with an MSO
n=56 not affiliated with an MSO
n=20 academic gastroenterologists

Secondary market analysis

Provided by Fraser Healthcare

Implications for Pharma

-  What are the perceived advantages and disadvantages to the MSO structure from the perspective of physician groups?
-  What is the process for practice induction to an MSO and what changes occur in structure (infusion service lines), protocols, contracting, and administrative management in these transactions?
-  What near, mid, and long-term strategic initiatives are these MSOs pursuing and how can pharma best align with these?

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- Report and custom readout - fieldwork conducted Q4 2020
- Quarterly newsletter updates on latest acquisitions and emerging trends throughout 2021
- Tailored, commercially-relevant insights