

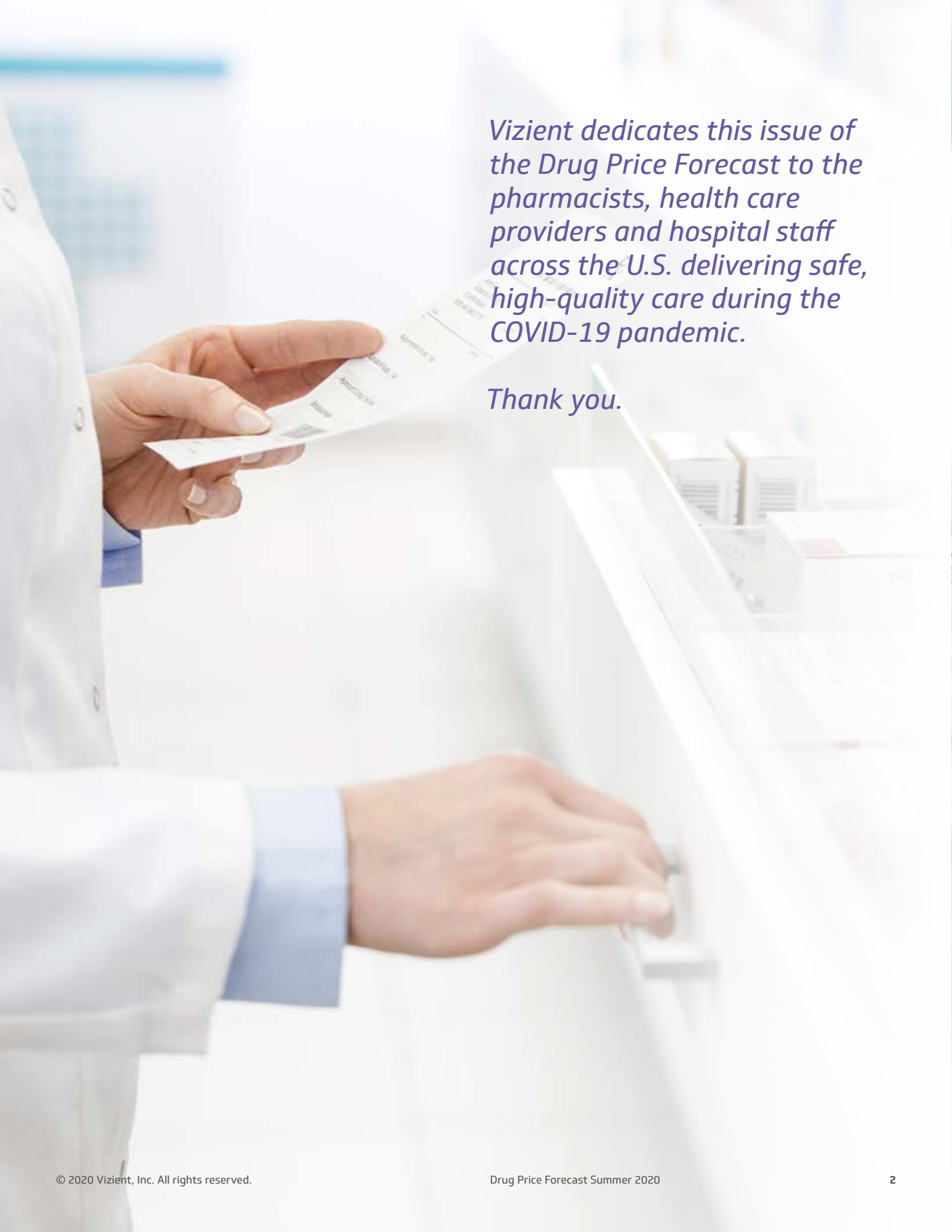


# Drug Price Forecast 2020

Summer 2020



Vizient Integrated Pharmacy Solutions

A close-up photograph of a pharmacist in a white lab coat. The pharmacist is holding a white prescription slip with both hands, looking at it intently. The background is a blurred pharmacy counter with various boxes and containers. The lighting is bright and clinical.

*Vizient dedicates this issue of the Drug Price Forecast to the pharmacists, health care providers and hospital staff across the U.S. delivering safe, high-quality care during the COVID-19 pandemic.*

*Thank you.*

## Forecast preparation, process and assumptions

Some things to keep in mind when reviewing the Drug Price Forecast:

- The forecast presents the Vizient® pharmacy team's best estimate of likely drug price behavior during the identified period. However, it is important to recognize the uncertainty inherent in the projection process.
- This analysis was conducted using data from Vizient Pharmacy Program participants' purchases (price and volume) in hospital and non-acute facilities. The product mix covered by this forecast is based on participants' aggregated purchases and will differ from that of any individual facility. To help you assess your own data using the information in this forecast, figures are presented using generic names and therapeutic categories. The Vizient Drug Budget Forecast Report may also be useful to you for capturing your institution's detailed pharmacy purchases. Contact us at [pharmacyquestions@vizientinc.com](mailto:pharmacyquestions@vizientinc.com) if you have questions about accessing the report.
- The products analyzed comprise the top 80% of pharmaceutical purchases (using dollars spent on a line-item basis) made through pharmacy Authorized Distributors by Vizient Pharmacy Program participants in hospital, non-acute, and pediatric settings from May 1, 2019 through April 30, 2020. Purchases made through the 340B program were excluded from the analysis. The analysis also does not include direct purchases.
- Purchasing sterile preparations from outsourced compounders is a sizeable expense for many health systems. This forecast does not analyze these purchases as they are not reported by our Authorized Distributors. If your facility uses outsourced compounding services, remember to factor those purchases into your budget. Vizient has noted regular price increases from our contracted suppliers in this area and we believe that this trend will continue.
- Vizient uses price change history for the last 36 months (where available), as well as experience and knowledge of current contract allowances and marketplace factors such as expiring patents and anticipated new competition, to develop an inflation estimate for each line item in the projection. The analysis does not take into account other market dynamics such as raw material scarcity and finished goods supply shortages.
- Information on possible patent expirations is provided solely as a courtesy and is based on sources available at the time of publication; actual expiration dates can change because of patent challenges and litigation processes. There is also no guarantee that an approved generic product will be ready to enter the market by the expiration date. Manufacturers also may file a request for exclusive marketing rights with the U.S. Food & Drug Administration (FDA) for periods ranging from 180 days to 7 years depending on the category. If granted, this period of exclusivity may or may not be synchronized with the patent status and can further delay the introduction of competition into the market.
- Information about new drugs in the pipeline is available by contacting [pharmacyquestions@vizientinc.com](mailto:pharmacyquestions@vizientinc.com). Cost information is not usually available for new products until they receive FDA approval; however, health care organizations should review the literature on any new agent to determine its place in therapy for their specific patient populations and to develop guidelines for cost-effective use of new, expensive drugs.

Disclaimer: This document is a projection of price behavior only. It is necessary to consider changes in volume and mix as well as the introduction and adoption of new drugs and other factors when preparing your drug expenditure budget.

This document is compiled based on information gathered from many primary and secondary sources, which Vizient believes to be accurate to the best of its knowledge at the time of publication. It is intended as general information only and is provided as an accommodation to members. Use of this data is at your sole risk. This information is presented "as is" and without any warranty or guarantee, expressed or implied, as to completeness or accuracy, or otherwise.

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## Letter from our group senior vice president, pharmacy solutions



**Dan Kistner, PharmD**

Group Senior Vice President,  
Pharmacy Solutions  
Vizient

Dear member,

Please allow me to express my deepest and most heartfelt appreciation for the work you have done and continue to do during this period of unprecedented crisis and change. My pharmacy team as well as other Vizient employees have been privileged to support you in your efforts to deliver quality care during these challenging and uncertain times. The COVID-19 pandemic has represented perhaps the greatest threat to global health we have witnessed in modern human history. We at Vizient have marveled at the resilience, agility and commitment demonstrated by our members as they have worked to fight this disease.

While the initial COVID-19 hot spots have seen a subsiding number of new cases, outbreaks continue throughout the country. As health care organizations attempt to resume a normal pattern of practice in this uncertain setting it is critical that we prevent the negative patient care experiences and economic outcomes from becoming even more severe and enduring. Furthermore, given the cost of COVID-19 in terms of patient lives, resource consumption and financial hardship, it would be truly inexcusable if we failed to implement a more consistent and durable health care system and associated supply chain capable of withstanding future disasters.

### Identifying, forecasting and sustaining access to essential medications

COVID-19 has presented many novel challenges, such as the need for both new direct treatments and vaccines. One particularly pervasive hardship has been the persistent and widespread lack of critical products, including personal protective equipment (PPE), diagnostic testing, life-sustaining devices such as mechanical ventilators and medications. However, some of the most pressing challenges already existed prior to the pandemic. As pharmacists know, drug shortages have presented a persistent challenge for the last two decades; however, COVID-19 has focused renewed attention on the ways in which supply interruptions impact care. It is our hope that the visibility of this problem — coupled with preexisting initiatives, such as our Novaplus® program — will continue to pave the way to permanent solutions.

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*COVID-19 has focused renewed attention on the ways in which supply interruptions impact care.*

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In October 2019, Vizient launched its Novaplus Enhanced Supply Program to secure additional inventory of medications deemed “essential” by our members and our internal clinical experts. This program now includes 17 molecules (approximately 92 national drug codes) for which Vizient — in partnership with suppliers — works to build product availability beyond that dictated by traditional usage patterns. One of the most prominent of these essential medications is propofol, a sedative critical to managing patients who require mechanical ventilation. Even though the expansion of inventory for propofol required by the Novaplus Enhanced Supply Program had not reached full maturation when COVID-19 was classified as a pandemic, this additional reserve provided members with access to over 676,000 units of this product that otherwise would not have been available. Although members were still challenged to meet the desired demand, the circumstances would have been even more dire in the absence of this preparatory production required by the program. Given the success of its program, Vizient is expanding this strategy to include more molecules, is continuing to revise and update its essential drugs list, and is increasing its level of engagement with suppliers to better understand the origination point for active pharmaceutical ingredients (API) and finished dosage forms.

## Advocacy and transparency

In addition to the Novaplus Enhanced Supply Program, the Vizient pharmacy team’s work with our Vizient Public Policy and Government Relations Office was another preexisting initiative that has paid dividends during the COVID-19 crisis. Over the last three years, Vizient has worked to establish and enhance relationships with numerous governmental and legislative stakeholders through congressional briefings, in-person meetings with organizations such as the FDA and numerous letters of comment on proposed regulatory changes. Thanks to these networks, Vizient has been well positioned to articulate critical messages on behalf of its members.

During the COVID-19 crisis, Vizient has been in routine (and often daily) contact with representatives of the FDA, the United States Drug Enforcement Administration (DEA), the Federal Emergency Management Agency, the National Governors Association and the White House Coronavirus Task Force. On March 16, 2020, Vizient sent a letter to this task force summarizing its recommendations for responding to the COVID-19 outbreak. These included easing restrictions on compounding pharmacies to produce greater quantities of drugs in short supply, expediting approvals for essential medications and increasing the allocation of pharmaceutical quotas for controlled substances — all of which have since been implemented. Vizient will continue to advocate on behalf of its members, particularly as attention turns toward correcting the problems exacerbated during the COVID-19 crisis.

At the beginning of the outbreak, there was substantial concern about shortages due to a decrease in the supply of API from foreign sources. Generally, those worries have not come to pass, with the primary challenge being supply far exceeding demand. Nevertheless, the heightened alarm about the U.S. reliance on foreign API and manufacturing has prompted interest in prioritizing the domestic production of pharmaceuticals. Vizient supports all initiatives that increase the capacity to manufacture essential, high-quality drugs, and additional investment in domestic manufacturing would be one way to achieve that goal. It must also be noted that during our two decades’ experience with

drug shortages, the majority of interruptions have been associated with quality issues at manufacturing locations, including those in the U.S. Therefore, Vizient remains focused on supporting a reliable and resilient supply chain of high-quality pharmaceuticals — in which the API origination point and manufacturing steps are more visible; the medications are manufactured domestically, where possible; and pharmaceuticals are housed within the U.S., as is the case with our Novaplus Enhanced Supply Program. Recognizing that we cannot eradicate drug shortages on our own, we also continue to work with numerous organizations that are advancing additional tactics to build expanded resiliency and capacity into the supply chain.

## Conclusions

The COVID-19 pandemic has created many changes not only in health care, but in all aspects of life. One thing that has not changed is our commitment to help members endure these difficulties and emerge even stronger. We are grateful to have had the opportunity to partner with our members during this time and are focused on working to create a health care delivery system that addresses the challenges revealed by COVID-19. Our Vizient Future of Health Care strategy has been developed to help members create personalized approaches to recovery and advancement using Vizient resources — enabling them to address not only the financial hurdles so many now face, but close the gap on delayed treatment needs for our communities. Our integrated pharmacy team of sourcing, analytics, advisory, network, member support and clinical experts stands ready to help you achieve and exceed your goals.

COVID-19 did not create new problems, but simply focused greater attention on issues that already existed. However, it has also illuminated the strength inherent in our membership and our organization, and we will continue to build on that foundation. I hope that together with our tools, resources and services you find this edition of the Vizient Drug Price Forecast beneficial as you continue on your path to better and more secure care for the populations you serve.

Respectfully,



# Projected timelines and approvals

● New drug approvals ● Regulatory and accreditation events ● Anticipated availability of new generics and biosimilars\*

July 2020-January 2021

## Belantamab mafodotin

Refractory/relapsed multiple myeloma  
Aug 1, 2020

## Viaskin Peanut (EPIT)

Peanut allergy  
Aug 5, 2020

## Oliceridine

IV opioid for postoperative pain with proposed lower side effect potential  
Aug 7, 2020

## Viltolarsen

Duchenne muscular dystrophy  
Aug 7, 2020

## KTE-X19

CAR-T for mantle cell lymphoma  
Aug 10, 2020

## Cedazuridine/decitabine

CML; myelodysplastic syndrome  
Aug 11, 2020

## Valoctocogene roxaparvovec

Gene therapy for hemophilia A (factor VIII deficiency)  
Aug 21, 2020

## Veverimer

Metabolic acidosis; oral, nonabsorbed polymer  
Aug 22, 2020

## Risdiplam

SMA (oral liquid)  
Aug 24, 2020

## Xaracoll (bupivacaine collagen-matrix implants)

Drug-device combination designed as a bioresorbable surgical implant for postsurgical pain  
Aug 26, 2020

## Satralizumab

Neuromyelitis optica (Devic's syndrome)  
Aug 28, 2020

## Tafasitamab

DLBCL  
Aug 30, 2020

## Terlipressin

Hepatorenal syndrome  
Sep 12, 2020

## Remestemcel-L

GVHD  
Sep 30, 2020

## Tramadol, IV

IV formulation for management of moderate to moderately severe pain  
Oct 10, 2020

## Pertuzumab/trastuzumab

Fixed-dose combination and subcutaneous formulation for breast cancer  
Oct 18, 2020

## Eflapegrastim

Long-acting G-CSF for chemotherapy-induced neutropenia; not a biosimilar  
Oct 24, 2020

## Atoltivimab/maftivimab/odesivimab

Ebolavirus infections (Ebola hemorrhagic fever)  
Oct 25, 2020

## Bronchitol (mannitol for inhalation)

Management of cystic fibrosis  
Nov 1, 2020

## Sutimlimab

Acquired (autoimmune) hemolytic anemia  
Nov 13, 2020

## Olanzapine/samidorphan L-malate

Bipolar disorder (manic depression); schizophrenia; schizophreniform disorder  
Nov 15, 2020

## Lisocabtagene maraleucel

CAR-T for DLBCL; FL; NHL; PCNSL; PMBCL  
Nov 16, 2020

## Lonafarnib

Hutchinson-Gilford progeria  
Nov 20, 2020

## Pralsetinib

NSCLC  
Nov 23, 2020

## Setmelanotide

Obesity  
Nov 27, 2020

## Naxitamab

Neuroblastoma  
Nov 30, 2020

## Idcabtagene vicleucel (ide-cel; bb2121)

CAR-T immunotherapy for multiple myeloma  
Nov 30, 2020

## Tanezumab

Subcutaneous biologic for osteoarthritis pain  
Dec 1, 2020

## Bertralstat hydrochloride

Oral, once daily for prevention of HAE  
Dec 3, 2020

## Lumasiran

Primary hyperoxaluria type 1  
Dec 3, 2020

## Margetuximab

Metastatic breast cancer in patients previously treated with anti-HER2 targeted therapies  
Dec 18, 2020

## Roxadustat

Oral treatment for anemia in CKD  
Dec 20, 2020

2020 Q3

## Bevacizumab (SB8)

Avastin  
Sep 2020

Q4

## Alvimopan

Entereg  
Nov 29, 2020

## Acetaminophen injection

Ofirmev  
Dec 6, 2020

## Rituximab (ABP 798)

Rituxan  
Dec 19, 2020

## Dasatinib

Sprycel  
Dec 28, 2020

## DSCSA

Wholesale distributor must verify a saleable returned product via the product identifier on each package or sealed homogeneous case before redistribution  
Nov 27, 2020

## USP Chapter <825>

Describes best practice and quality standards for the preparation, compounding, dispensing and repackaging of radiopharmaceuticals; for informational purposes only and not compendially applicable  
Dec 1, 2020

\* Projected dates of loss of exclusivity for originator drugs and generic or biosimilar entrants to the market are subject to change.

Abbreviations: CAR-T = chimeric antigen receptor T cell; CKD = chronic kidney disease; CML = chronic myelogenous leukemia; DLBCL = diffuse large-B-cell lymphoma; DSCSA = Drug Supply Chain Security Act; EPA = Environmental Protection Agency; EPIT = epicutaneous immunotherapy; FDA = U.S. Food & Drug Administration; FL = follicular lymphoma; G-CSF = granulocyte colony-stimulating factor; GVHD = graft versus host disease; HAE = hereditary angioedema; HER2 = human epidermal growth receptor 2; IV = intravenous; NHL = non-Hodgkin lymphoma; NSCLC = non-small-cell lung cancer; PCNSL = primary CNS lymphoma; PD-1 = programmed cell death protein 1; PDUFA = Prescription Drug User Fee Act; PMBCL = primary mediastinal B-cell lymphoma; RCRA = Resource Conservation and Recovery Act; SCLC = small-cell lung cancer; SMA = spinal muscular atrophy; USP = United States Pharmacopeia.



# Projected timelines and approvals

● New drug approvals ● Regulatory and accreditation events ● Anticipated availability of new generics and biosimilars\*

July 2020-January 2021

## Dostarlimab

Anti-PD-1 antibody for second-line treatment of recurrent endometrial cancer  
Jan 4, 2021

## Voclosporin

Lupus nephritis  
Jan 26, 2021

## Pegunigalsidase alfa (PRX-102)

Fabry disease  
Jan 27, 2021

## Dasiglucagon

Hypoglycemia  
Mar 27, 2021

## Tivozanib hydrochloride

Metastatic renal cell carcinoma  
Mar 31, 2021

## Ropeginterferon alfa-2b

Polycythemia vera  
Apr 5, 2021

## Management Standards for Hazardous Waste Pharmaceuticals (Part 266 Subpart P)

EPA Final Rule allows pharmaceutical reverse distributors and health care facilities that manage hazardous waste to exclude hazardous waste pharmaceuticals from regulation under the more stringent RCRA hazardous waste management standards

Jul 1, 2021, in authorized states not requiring a statutory amendment to adopt Subpart P

Jul 1, 2022, in authorized states requiring a statutory amendment to adopt Subpart P

2021 Q1

Q2

Q3

Q4

## Cabazitaxel

Jevtana  
Mar 1, 2021

## Bevacizumab (MYL-14020)

Avastin  
Mar 27, 2021

## Degarelix acetate

Firmagon  
May 2, 2021

## Romidepsin

Istodax  
Aug 1, 2021

## Emtricitabine/tenofovir disoproxil fumarate

Truvada  
Sep 9, 2021

## Efavirenz/emtricitabine/tenofovir disoproxil fumarate

Atripla  
Sep 9, 2021

**Nebivolol hydrochloride**  
Bystolic  
Sep 27, 2021

## Lenvatinib mesylate

Lenvima  
Oct 19, 2021

## Trabectedin

Yondelis  
Nov 1, 2021

## Nebivolol

Bystolic  
Dec 1, 2021

## Dabigatran etexilate mesylate

Pradaxa  
Dec 1, 2021

\* Projected dates of loss of exclusivity for originator drugs and generic or biosimilar entrants to the market are subject to change.

Abbreviations: CAR-T = chimeric antigen receptor T cell; CKD = chronic kidney disease; CML = chronic myelogenous leukemia; DLBCL = diffuse large-B-cell lymphoma; DSCSA = Drug Supply Chain Security Act; EPA = Environmental Protection Agency; EPIT = epicutaneous immunotherapy; FDA = U.S. Food & Drug Administration; FL = follicular lymphoma; G-CSF = granulocyte colony-stimulating factor; GVHD = graft versus host disease; HAE = hereditary angioedema; HER2 = human epidermal growth receptor 2; IV = intravenous; NHL = non-Hodgkin lymphoma; NSCLC = non-small-cell lung cancer; PCNSL = primary CNS lymphoma; PD-1 = programmed cell death protein 1; PDUFA = Prescription Drug User Fee Act; PMBCL = primary mediastinal B-cell lymphoma; RCRA = Resource Conservation and Recovery Act; SCLC = small-cell lung cancer; SMA = spinal muscular atrophy; USP = United States Pharmacopeia.

## Executive summary

The Summer 2020 Drug Price Forecast is our best estimate of the change in the price of pharmaceuticals that Vizient Pharmacy Program participants will be purchasing between Jan. 1-Dec. 31, 2021. The forecast focuses on pharmaceutical products used across multiple health system settings, including inpatient and non-acute environments, and provides a year-over-year estimate of the expected price change.

Price change predictions for contract and noncontract product segments are shown in Table 1, along with the overall drug price inflation number for existing drugs as calculated by Vizient.

### What does the overall projection tell us?

Although there has been tremendous uncertainty in many aspects of drug utilization during COVID-19, key metrics related to health care have maintained a degree of continuity. As reported in recent iterations of this forecast, the general trend for drug pricing continues to moderate. Generic competition and biosimilars have curbed the impact of routine price increases for frequently used medications. However, this is not always the case: For example, substantial price increases are anticipated for adalimumab prior to the launch of biosimilar competition in 2023. Also, as has been shown in previous forecasts, the impact of Vizient contracting cannot be overstated. Compared to contracted products, the estimated price increases for noncontracted drugs are anticipated to be four times higher. Vizient is working every day to expand its contract coverage through its national portfolio as well as its community of pharmacy aggregation networks.

### The COVID-19 conundrum

As we routinely advise, the Vizient Drug Price Forecast projections are estimates of pricing behavior. In addition to price, the extent to which medications are used is a

critically relevant issue, particularly during this pandemic crisis. Given the uncertainty regarding the spread of COVID-19 for the remainder of 2020 and into 2021, members must be extremely cognizant of variations in medication use trends and the impact of total expenditures.

An example of this variability can be seen in the most recent forecast projection published by the *American Journal of Health-System Pharmacy* (AJHP), which shows that volume and mix for calendar year 2019 increased 10.9% in the clinic setting, but decreased 0.6% in the nonfederal hospital environment.<sup>1</sup> Given the increased utilization patterns in critical care and the decrease in primary care visits and outpatient services, that trend has been greatly altered during this pandemic. The AJHP article also notes that the change in total expenditures attributable to the introduction of new products in calendar year 2019 was 2% in the clinic setting and 1.3% for nonfederal hospitals.<sup>1</sup>

As a result, we encourage members to use the Vizient [Drug Budget Forecast Report](#) to apply the projections in the Vizient forecast to their unique purchasing patterns. The Drug Budget Forecast Report also enables members to adjust their projections based on changes in utilization, such as those that have been seen with COVID-19.

Vizient remains focused on providing members with the greatest value through our national portfolio — whether purchasing habits are consistent or practice patterns are changing greatly. We will continue to provide more information as additional updates about the financial impact of COVID-19 become available.

1 Tichy EM, Schumock GT, Hoffman JM, et al. National trends in prescription drug expenditures and projections for 2020. *Am J Health Syst Pharm*. Published online May 15, 2020. doi: 10.1093/ajhp/zxaa116

**Table 1. Summary of projected drug price inflation, Jan. 1-Dec. 31, 2021**

Product group	Vizient predicted price change, %	Percentage of analyzed group	Estimated price change weighted by Vizient purchases, %
Contract products	1.80	36.95	0.67
Noncontract products	4.15	63.05	2.62
<b>Total weighted average drug price inflation estimate</b>			<b>3.29</b>

Estimates based on Vizient member data.

## Future of health care

### Acute care

For the past several decades, the overall focus of health care has been on migrating care to non-acute settings, a trend that has been mirrored in health systems' investment focus (e.g., expansion of specialty, retail and pharmacy benefit) and the majority of the medications in the investigational drug pipeline. While that focus will continue, the COVID-19 outbreak has reframed the relevance and importance of critical care. The pandemic and the high number of patients who have required invasive intensive care, including mechanical ventilation, illustrate how important it is to have robust systems and necessary "essential" medications to manage people with high levels of acuity. Going forward, we will need to concentrate on expanding our non-acute footprint, including virtual care. However, we can never lessen or lose our capacity to deliver quality critical care.

#### Beyond COVID-19

Table 2 shows the distribution of drug spend for the 10 medications that account for the most acute care spend among Vizient member organizations. As the table illustrates, there are definitive trends unrelated to COVID-19. First, the biosimilar effect continues to take hold. The traditional budget behemoths — infliximab and pegfilgrastim — have continued to decline as the market sees an increasing number of biosimilars. While the launch of competitive products has taken longer, biosimilars for rituximab, bevacizumab and trastuzumab are increasingly eroding the financial impact of their branded counterparts. As a result, newer branded biologics such as pembrolizumab, nivolumab and ocrelizumab now occupy positions of dominance. In addition, the prevalence of injectable acetaminophen as a prominently featured high-spend drug will likely end with the anticipated launch of multiple generics at the end of 2020.<sup>1</sup> Purchases of immune globulin remain high. Due to the decreasing number of donors during the outbreak and the anticipated higher interest in convalescent and other forms of plasma as future treatment alternatives, we anticipate the market to remain tight as described in the therapeutic section on [plasma critical care products](#). Even though we continue to measure the total impact of the COVID-19 pandemic, the effect on drug spending is clear.

**Table 2. Top 10 drugs by acute care spend among Vizient members**

Rank	Drug name
1	Pembrolizumab
2	Rituximab
3	Alteplase
4	Nivolumab
5	Pegfilgrastim
6	Immune globulin, gamma (IgG)/proline/IgA 0 to 50 mcg/mL
7	Infliximab
8	Bevacizumab
9	Vasopressin
10	Ocrelizumab

Based on Vizient internal data.

The COVID-19 outbreak both reinforced the relevance of high-capacity, high-quality critical care interventions and reflected the weaknesses that make delivery of these types of clinical services challenging. The novelty of the illness, the uncertainty of how to provide supportive care and patient management (e.g., the role of corticosteroids, appropriate anticoagulation and cytokine inhibitors), and the lack of definitive data to answer these questions made the selection of therapeutic options difficult. Although some of those gaps in knowledge have been [filled in](#), how best to manage the financial consequences remains an open question.

Table 3 shows the top 10 drugs associated with COVID-19 patients, with the greatest dollar spend increase occurring in March and April 2020, compared to those same months in 2019. Each of these drugs had over a \$5 million increase in acute care spend for the membership; the combined increase in spend for all of these drugs was approximately \$200 million.<sup>2</sup> Not every purchase was associated with a COVID-19 patient; however, given the almost complete cessation of elective surgery procedures, a substantial amount can be attributed to the outbreak.

**Table 3. COVID-19 acute care drugs with the greatest increase in spend (March-April 2019 versus March-April 2020)**

Drug name	Increase in spend, %	Increase in units purchased, %
Tocilizumab	438	250
Vasopressin	107	84
Albuterol sulfate	221	93
Dexmedetomidine	142	146
Propofol	56	24
Cisatracurium	188	250
Epinephrine	48	29
Hydroxychloroquine	1,132	1,253
Norepinephrine bitartrate	81	115
Fentanyl citrate	100	64

Based on Vizient member data.

As the investigational pipeline has changed to more outpatient and/or dispensed drugs, pharmacy leaders have historically taken some comfort that the increase in their budgets would to some extent be offset by higher revenue, as the products in question were separately reimbursable. The expense of inpatient medications is not mitigated by additional reimbursement.

### Novaplus Enhanced Supply Program and essential medications

Beyond which drugs to use, the second critical concern for the acute care environment is the potential inability to obtain needed medications. At the onset of COVID-19, the initial fear was that the outbreak in China and other foreign areas would negatively affect the supply of API or other components needed to provide finished dosage forms. Largely, that outcome did not occur. Instead, the overwhelming demand, as shown in Table 3, exceeded supply capacity. As pharmacists know, drug shortages did not originate with COVID-19. However, the crisis has illustrated the fragility of the supply channel and the tremendous risk it presents for patient care. While there have been multiple projects targeting drug shortages, Vizient launched two projects prior to COVID-19 that have helped during this crisis and have paved the way for future supply resiliency: the Novaplus Enhanced Supply Program and the identification of essential medications that, if not available, would greatly impact the timely and quality delivery of patient care.

In 2019, Vizient conducted a comprehensive drug shortages survey of its members; the results showed that ongoing challenges with medication supplies result in an additional \$360 million in labor expense across the U.S. every year. To address this issue, Vizient launched the Novaplus Enhanced Supply Program, an enhancement to the long-standing Vizient private label program that enables Vizient to partner with key suppliers to plan additional inventory of essential medications. These pharmaceuticals are critical to providing lifesaving care as determined by current clinical guidelines, member feedback and the expertise of our internal clinicians. Fresenius Kabi was the first supplier partner to join the program in November 2019, and was able to supply an additional **676,000 units** of propofol (20-mL, 50-mL and 100-mL vials) during March through April 2020 — the peak of the COVID-19 outbreak. While obtaining adequate supply of this product was still challenging, the experience would have truly been catastrophic had this program not been in place. This type of strategic sourcing approach to providing consistent access to the most essential medications will remain a focus for Vizient as we prepare for continuing outbreaks of COVID-19 and other potential disruptions.

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*The Vizient Novaplus Enhanced Supply Program has helped blunt shortages of the most sought-after drugs during the COVID-19 pandemic.*

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## Life after COVID-19

Given the dramatic changes that clinicians have experienced, it is clear we must drastically alter our approach to practice. Certainly, we need new and proven treatments and vaccines for COVID-19. And, a further understanding of its disease state processes will enable us to better treat this illness. However, we must address the weaknesses of the current supply and learning processes to create a more resilient environment of care, including:

- **Solving drug shortages permanently.** As we have mentioned, COVID-19 did not create drug shortages — it just made a bad situation worse. Therefore, we must maintain and amplify our efforts to fix the fragility of the supply chain once and for all. Therefore, we encourage members to maximize the value of Novaplus, including accessing an additional inventory of lifesaving drugs through the Novaplus Enhanced Supply Program, as we continue to add products to this category. We also encourage members to review our recently updated [Vizient essential medications list](#) to ensure their organizations know which drug products to use during various crises. The next disaster to impact the supply of essential medications may not be a pandemic.
- **Creating a continual and rapid learning cycle for clinical practice.** As mentioned in this section and [elsewhere](#) in this forecast, clinical information is becoming available at an accelerated rate. Unfortunately, the quality and depth of this information is inversely proportional to the rate at which it is released. As a result, pharmacists — in conjunction with their prescriber partners — will have to

ensure they keep abreast of the most recent information, while judiciously assessing the quality of the evidence. Our clinical reports, pharmacotherapy for COVID-19 [evidence summary](#) and [clinical controversies](#) resources continue to be updated with information regarding COVID-19, and we are working on developing similar clinical resources for the continuing cultivation of new insights regarding treatment and management.

- **Maintaining a high level of care.** The emphasis on care provided in the intensive care unit as well as critical care has hopefully called attention to ways in which we can improve practice. Given that drug expenditures are moving away from the inpatient setting, it is possible our organizations have devoted less resource capacity to high-acuity practice. While we must develop new ways of meeting patients' needs (e.g., virtual care), we must also ensure our pharmacists' and technicians' skill sets are at the levels needed to provide quality care during a crisis. Vizient will continue to offer continuing education [opportunities](#) on these critical practice competencies.

Organizations must create and implement plans that will enable practices to continue functioning effectively even in the event of a COVID-19 resurgence or the occurrence of a different disaster. More information on our support capabilities are available [here](#).

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- 1 IPD Analytics Biologics/Biosimilars Database. IPD Analytics; 2020. Accessed June 6, 2020. [www.ipdanalytics.com](http://www.ipdanalytics.com)
  - 2 Vizient internal data.





# Non-acute care

## New opportunities to deliver care

The COVID-19 outbreak directed the focus and attention of hospitals and health systems toward the delivery of critical care. The ability to deliver invasive support required that labor, technology and medication resources were quickly directed toward this service. As a result, many aspects of care that occur in the non-acute setting (e.g., outpatient clinic, physician office and surgery center) were negatively impacted. Primary care patient visits, preventive treatments, diagnostic interventions and nonurgent surgical procedures all trended downward during the pandemic, causing financial hurdles and potential long-term, negative clinical consequences. However, this experience has also created a tremendous opportunity given the need for care delivery with less in-person interaction and in settings removed from the critical care environments where COVID-19 patients are treated. If there was ever any hesitancy regarding the expansion of medication management services through retail pharmacy, specialty pharmacy practice, home infusion and telepharmacy capabilities, the COVID-19 experience has validated the strategic relevance of these functions.

Table 4 shows the current top 10 non-acute drugs list, which appears remarkably similar to the lists seen in recent iterations of the forecast. Biologic drugs used to manage oncology, neurology, rheumatology and other related specialty conditions occupy the top spend positions. While five biosimilars of adalimumab have been approved and others are still in development, none of these products will reach the market before 2023.<sup>1</sup> However, we are seeing erosion in originator spend where biosimilar competition is available. We expect similar growth in outpatient, chronic and specialty pharmaceuticals, all of which are in the [investigational pipeline](#). Still, we must acknowledge the impact of COVID-19, both in its near-term financial effects and the potential for future disruptions.

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*We are seeing erosion in originator spend where biosimilar competition is available.*

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**Table 4. Top 10 drugs by non-acute care spend among Vizient members**

Rank	Drug name
1	Adalimumab
2	Ustekinumab
3	Etanercept
4	Infliximab
5	Etelcalcetide hydrochloride
6	Denosumab
7	Secukinumab
8	Rituximab
9	Sofosbuvir/velpatasvir
10	Certolizumab pegol

Based on Vizient internal data.

## COVID-19: disrupting non-acute care

COVID-19 caused a significant amount of disruption in the non-acute setting due to the cancellation and delay of elective surgery procedures, a decrease in laboratory and diagnostic testing, and a decline in primary care visits.<sup>1</sup> Per our Emergency Practices Dashboard that was established to assess the impact of COVID-19 on member services, about 72% of respondents stopped performing elective procedures from mid-March to mid-April 2020.<sup>2</sup> As of June 3, 2020, about 53% of respondents reported a resumption of elective procedures.<sup>2</sup> Obviously, the COVID-19 outbreak has affected some areas to a greater degree than others and some member organizations may have had a greater ability to accelerate their recovery efforts in this setting. Still, the sustained impact remains substantial.

The impact has been similarly felt on laboratory and diagnostic testing, as shown in Table 5. In a recent analysis conducted by IQVIA, a health data information management company, the percentage of laboratory tests decreased at least 74% across different care settings (e.g., office, urgent care and independent lab) between early February through April 3, 2020.<sup>3</sup> In addition, numerous oncology screening procedures were similarly disrupted when comparing February 2020 data to the period ending the week of April 10, 2020.<sup>3</sup>



**Table 5. Decrease in diagnostic screenings for oncology due to COVID-19 impact on nonessential visits**

Mammograms (% decrease)	Pap smears (% decrease)	Colonoscopies (% decrease)	CT scans (% decrease)	PSA tests (% decrease)
87	83	90	39	60

Data derived from IQVIA Institute website.<sup>1</sup>

Abbreviations: CT = computed tomography; PSA = prostate-specific antigen.

### Similar trends for pharmaceuticals

When comparing March and April 2019 to the same two months in 2020, the expenditures for many types of drugs decreased.<sup>3</sup> Table 6 reflects changes in spend and units purchased that were seen across physician offices and clinics within the Vizient contract roster.<sup>3</sup> While some of these changes could be attributed to decreases resulting from the purchase of generics and biosimilars (which are beneficial), there are other changes that are more worrisome.

**Table 6. Pharmaceuticals with the greatest decrease in spend (March-April 2019 versus March-April 2020): Vizient physician offices and clinics**

Rank	Drug	Change in spend, %	Change in units purchased, %
1	Cinacalcet HCl	-91	-71
2	Epoetin alfa	-79	-67
3	Infliximab	-27	-4
4	Denosumab	-12	-16
5	Testosterone	-82	-44
6	Hyaluronate sodium	-46	-39
7	Collagenase clostridium histolyticum	-35	-17
8	Human papillomavirus vaccine, 9-valent/PF	-40	-44
9	OnabotulinumtoxinA	-35	-36
10	Pneumococcal 13-valent conjugate vaccine (diphtheria crm)/PF	-16	6

Based on Vizient internal data.

Spending on numerous vaccines also substantially decreased in March and April of 2020 compared to the same two months in 2019 (Table 7).<sup>3</sup> It is unclear what the long-term clinical and financial impact will be on patients whose diagnoses have been delayed or who have increased susceptibilities to preventable diseases. Going forward, one of the main goals will be to identify these patients and ascertain whether they might need increased, more invasive care.

**Table 7. Top 10 vaccines with decreased spend (March-April 2019 versus March-April 2020): all Vizient non-acute classes of trade**

Rank	Drug	Change in spend, %	Change in units purchased, %
1	Human papillomavirus vaccine, 9-valent/PF	-42	45
2	Pneumococcal 13-valent conjugate vaccine (diphtheria crm)/PF	-19	0.3
3	Measles, mumps and rubella vaccine live/PF	-56	-59
4	Measles, mumps, rubella and varicella vaccine live/PF	-45	-48
5	Meningococcal vaccine A, C, Y and W-135, diphtheria toxoid conj/PF	-42	-43
6	Hepatitis A virus vaccine/PF	-40	-41
7	Hepatitis B virus vaccine recombinant/PF	-11	-10
8	Meningococcal group B vaccine, 4-component	-49	-74
9	Diphtheria, pertussis (acellular), tetanus vaccine/PF	-27	-37
10	Varicella virus vaccine live/PF	-19	-23

Based on Vizient internal data.

## Changing the delivery of care — virtually

While non-acute care has been impacted by COVID-19, delivering care and providing treatment outside of an inpatient setting has become even more desirable and has created numerous opportunities for providers. Telemedicine is one strategy that has been increasingly used: A recently reported analysis showed that on average, 23% of physician-patient interactions in the U.S. for the week ending April 3, 2020, were conducted virtually.<sup>1</sup> For certain disciplines such as gastroenterology, allergy, rheumatology, endocrinology and primary care, that percentage was even higher.<sup>1</sup> For psychiatry, the percentage of virtual physician-patient interactions exceeded 50% during this time period.<sup>1</sup> Although this increased use of technology did not offset all of the decreases in physician visits, it does represent an opportunity for expanded delivery of medical and pharmacy care. Telepharmacy is another area in which clinical consultation and medication management services can be provided and will expand; as a result, the delivery of medications in the home setting will also increase.<sup>4</sup>

As shown in Table 4, many of the medications that dominate spend are infused products. As a result, efforts will continue to focus on delivering these therapies in non-acute settings. Given the challenges of keeping patients critically ill with COVID-19 separated from others in the health system setting, as well as the reluctance of non-COVID-19 patients to enter hospitals, the home infusion setting is becoming increasingly popular. During the COVID-19 crisis, the Centers for Medicare & Medicaid Services (CMS) temporarily relaxed provisions for home infusion therapy services related to billing, contracting with physicians, remote monitoring and coverage determinations.<sup>5</sup> Due to the success of this level of expansion, we anticipate continued and increasing interest in home infusion care for the delivery of many types of medications, including oncology products, although the extent of this service remains controversial.

## Next steps

- **Recovering capacity and delivery of care.** One of the most important areas of focus during the next few months is ensuring that non-acute services that were interrupted or delayed by COVID-19 are able to resume full functioning as much as possible to provide needed care. A large number of missed diagnostic and laboratory tests, as well as delayed vaccines and pharmaceutical interventions, can lead to adverse outcomes and higher costs. Provista® and Vizient are willing and able to help members accelerate their capabilities as quickly as possible.
- **Expanding non-acute services.** The COVID-19 experience has highlighted the critical need to diversify not only the types of services that are provided (e.g., retail and specialty), but also the technologies used to offer these services (e.g., telepharmacy). Therefore, members must assess whether they can withstand interruptions to care delivery. Again, both Provista and Vizient have numerous subject matter experts able to help identify these opportunities.

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# Specialty pharmaceuticals

## A continued increase in sales

Specialty pharmacy growth continues to outpace growth of the traditional pharmacy market, with specialty pharmaceuticals accounting for 48% of all nondiscounted pharmacy spend. In comparison, just five years ago, specialty pharmacy accounted for only 38% of the market. As we look across the different pharmacy sectors, we see an even higher share of sales for specialty pharmaceuticals in the mail order and nonretail (i.e., health systems) settings (80% and 66%, respectively).<sup>1</sup>

These trends have not slowed down in the era of COVID-19. Data submitted to Acentrus™ appears to have shown a marked increase in the number of prescriptions filled by member specialty pharmacies beginning in early March and continuing through May.

Numerous factors may have contributed to a surge in prescriptions, including:

- **Centers for Disease Control and Prevention (CDC) guidance.**<sup>2,3</sup> When considering the potential for shelter-in-place orders and quarantine, the CDC advised the general public to have extra medications on hand (i.e., several weeks' supply for higher-risk patients).
- **Fears over drug shortages.** This topic continues to make headlines, highlighting U.S. reliance on foreign importation of API and drug products as well as reports of suppliers struggling to meet demand.

- **Change in prescribing practices.**<sup>4</sup> Due to COVID-19, there has been a shift from administering intravenous medications in a clinic setting to administering agents at home (i.e., oral agents and intramuscular or subcutaneous medications).
- **Rise in unemployment rates.**<sup>5,6</sup> From February to May 2020, the unemployment rate rose by 9.8%, resulting in an additional 15.2 million Americans being out of work. With the loss of their insurance looming on the horizon, it is feasible that patients may have stocked up on medications while still covered by insurance. It will be interesting to watch patient care trends in the coming months (i.e., what percentage of patients will be forced to forgo treatment) as well as the impact on reimbursement as more patients move to Medicaid.
- **Relaxed approval of drug refills.**<sup>7</sup> Insurers have made it easier for patients to fill medications by loosening restrictions on 90-day refills, prior authorizations and filling medications days to weeks ahead of time.

Due to COVID-19, Bristol-Myers Squibb elected to delay commercialization of ozanimod (Zeposia) until June 2, 2020.<sup>8</sup> This highly anticipated oral therapy for multiple sclerosis (MS) — which requires no genetic test or first-dose observation at initiation — was approved by the FDA on March 25, 2020. It remains to be seen if COVID-19 will impact the approval and launch of additional pipeline products in 2020.



## Specialty projections, Jan. 1, 2021–Dec. 31, 2021

Since 2019, Vizient has provided projections on the inflation rate for specialty drugs. A total of 172 drugs and 545 NDCs met the criteria for being considered a specialty drug in the current analysis. Factors that contributed to the specialty classification included:

- Limited-distribution drugs
- High cost: threshold set at > \$4,000 per month
- Treats a rare or orphan disease state
- High touch: requires frequent clinical monitoring and patient education to ensure safety
- Requires a specialist prescriber

In analyzing historical price trends, market conditions and member spend for these agents, the current projected specialty drug price inflation rate is 4.47%.

Table 8 provides a high-level summary of our analysis, with specialty drugs being classified as either biologic or nonbiologic products.

It should be noted that the projected specialty inflation rate of 4.47% is much higher than both the general drug inflation rate predicted for this same time period (3.29%) as well as the specialty inflation rate predicted for the July 1, 2020–June 30, 2021 time frame (3.36%; see January 2020 edition of the [Drug Price Forecast](#)). With adalimumab (Humira) being the highest contributor to total drug spend for Vizient members (see Table 3) and a newly predicted inflation rate of 7.4%, it should come as no surprise that this agent is the main reason for the rise in the predicted specialty inflation rate. Unfortunately, approved adalimumab biosimilars — which will introduce price competition — are not anticipated to launch until 2023.<sup>9</sup>

**Table 8. Estimated specialty drug price inflation rates, Jan. 1, 2021–Dec. 31, 2021**

Product group	Vizient predicted price change, %	Percentage of analyzed group	Estimated price change weighted by Vizient purchases, %
Biologics	4.48	70.06	3.14
Nonbiologics	4.45	29.94	1.33
<b>Total weighted average drug price inflation estimate</b>			<b>4.47</b>

Estimates based on Vizient member data for May 1, 2019–April 30, 2020.

## Summary

Specialty growth continues to outpace that of traditional pharmacy, with specialty pharmaceuticals accounting for roughly half of all nondiscounted pharmacy spend. Although COVID-19 undeniably complicated access to patient care and pharmaceuticals, sales of specialty pharmaceuticals surged during the pandemic. The expansion of specialty pharmaceuticals — along with a much higher than predicted inflation rate compared to the general drug inflation rate — highlights the need for a defined specialty pharmacy strategy for health systems. Along with Acentrus, we continue to enhance our offerings to address a rapidly changing market and provide solutions to the challenges that our members face.

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# Pediatrics



3.16%

Pediatric inflation rate

[Vizientinc.com resource](#)  
[Vizient pediatric program](#)

Unlike most areas of patient care, the pediatric population has been less affected by the COVID-19 pandemic. The most significant changes have been due to mandated safety measures, and include reductions in routine health service appointments and missed early diagnostic opportunities. In some highly affected areas, pediatric practitioners have been asked to support the large volume of adult patients; in addition, children's hospitals are being asked to treat young adults not presenting with COVID-19 symptoms. This has resulted in adjustments in drug spend and quantity due to the larger patient population variance.<sup>1</sup>

Drug approvals for the pediatric population have remained focused in three categories: specialty drugs, gene therapy and chimeric antigen receptor (CAR) T-cell treatments. All three of these treatments present budgetary and revenue capture obstacles; therefore, additional evaluations must be made before including these medications in hospital formularies. The value-based approaches include evaluating quality-adjusted life year, outcomes-based payments and indication-based pricing.<sup>2</sup> Approximately 80% of known rare diseases are based on genetic mutations. Of the 10 gene therapy products commercially available, half are used to treat pediatric patients. Gene therapy implementation led the high-cost target drug list in pediatrics from 2019 into early 2020. Due to the nature of the research focused on COVID-19 treatments and prevention, we are seeing a delay in the start of new trials, with existing trials not currently adding new patients.

## Recent approvals

In January 2020, arachis hypogaea (Palforzia-AR101; Aimmune), an oral immunotherapy indicated for the mitigation of allergic reactions to peanut protein, was approved by the FDA. The goal is to build immunity to peanut protein by gradually increasing the dose to provide a desensitization over a period of six months.<sup>3</sup> More than 550 participants enrolled in the Peanut Allergy Oral Immunotherapy Study of AR101 for Desensitization in Children and Adults (PALISADE), and by the end of the study, 67% of patients were able to withstand 600 mg of peanut protein. Aimmune has set the list price of AR101 at \$890 per month (an estimated \$10,700 annual cost). The FDA has required a Risk Evaluation and Mitigation Strategy (REMS) program for this drug, with the first dose completed in the hospital setting.<sup>3</sup>

Selumetinib (Koselugo; AstraZeneca), approved in April, treats neurofibromatosis type 1 in patients with plexiform neurofibromas that cannot be completely resected. This novel treatment's oral dosage has a wholesale average price of \$363.50 per tablet, a cost that is offset by billing and reimbursement coverage by most insurance in the outpatient space.<sup>4</sup>

Avexis is anxiously awaiting FDA approval to resume its Study of Intrathecal Administration of Onasemnogene Apeparvovec-xioi for Spinal Muscular Atrophy (STRONG) this summer. Onasemnogene apearvovec-xioi (Zolgensma) is a gene therapy that treats type 2 and 3 spinal muscular atrophy (SMA). The study was halted in late 2019 due to dorsal root ganglia mononuclear inflammation seen in animal studies<sup>5</sup>; however, Zolgensma is still available as an intravenous infusion for SMA type 1. Patients with types 2 and 3 can obtain treatment with the alternative intrathecal nusinersen (Spinraza; Biogen).<sup>6</sup>



## Cost increases driven by specialty drugs, outpatient care

Pediatric pharmaceutical costs are rising as a result of the targeting of rare diseases that require specialty or orphan drugs. Based on purchase data for self-governed children’s hospitals that participate in the Vizient Pharmacy Program, we predict the inflation rate for pediatric pharmaceuticals to be 3.16%.

Table 9 lists the top 10 drugs based on total expenditures among self-governed children’s hospitals, the drugs’ ranking from the January 2020 Drug Price Forecast and overall spend among Vizient members for May 1, 2019, through April 30, 2020. Dinutuximab (Unituxin; AbbVie), indicated for high-risk neuroblastoma, has retained its position as the highest-spend drug for multiple years. Pegaspargase (Oncaspar; Shire), a modified enzyme used to treat acute lymphoblastic leukemia, and infliximab (Remicade; Janssen Biotech, Inc.), a monoclonal antibody used in the treatment of autoimmune diseases, have remained in the top three for year-over-year spend.

New to the top 10 is defibrotide (Defitelio; Jazz Pharmaceuticals), indicated for the treatment of hepatic veno-occlusive disease, also known as sinusoidal obstruction syndrome.<sup>7</sup> Its side effect profile and restricted usage caused it to be a slow mover in the pediatric space. However, Jazz Pharmaceuticals and Children’s Oncology

Group recently collaborated on several publications and clinical presentations that highlight its improved survival and safety profiles.<sup>8</sup>

Due to the costs of the newer novel therapies and drug shortages, hospitals have had to seek out alternative treatments, likely affecting many typical top 10 drugs for self-governed children’s hospitals, such as sildenafil (Revatio; Pfizer) and eculizumab (Soliris; Alexion).

The high cost of CAR-T and gene therapy agents such as tisagenlecleucel (Kymriah; Novartis), voretigene neparvovec (Luxturna; Spark Therapeutics) and onasemnogene abeparvovec-xioi (Zolgensma; Novartis) remains a consideration for pediatric care centers. On the horizon is the highly anticipated approval of risdiplam (RG7916; Genentech). The original Prescription Drug User Fee Act date of May 25, 2020, was delayed to August 24, 2020, to enable more clinical trial data to be submitted for patients from 2-25 years of age with SMA types 2 and 3 (SUNFISH part 2-NCT02908685).<sup>9</sup> Risdiplam will be an alternative oral home therapy to intrathecal nusinersin (Spinraza; Biogen) antisense therapy and intravenous onasemnogene abeparvovec-xioi gene therapy; the convenience of at-home administration will be critical to parents and patients. At the same time, the revenue and cost associated with nusinersin (Spinraza; Biogen) and onasemnogene abeparvovec-xioi — which costs \$2.1 million for a single infusion<sup>10</sup> — will significantly decrease. The pricing strategy of risdiplam is under review

**Table 9. Top 10 pediatric drugs based on spend<sup>a</sup> among self-governed children’s hospitals that participate in the Vizient GPO**

Current ranking among children’s hospitals <sup>b</sup>	Previous ranking among children’s hospitals <sup>c</sup>	Generic drug name (brand name; manufacturer)	Current ranking among all Vizient members <sup>b</sup>
1	1	Dinutuximab (Unituxin; United Therapeutics)	86
2	2	Pegaspargase (Oncaspar; Baxalta)	10
3	3	Infliximab (Remicade; Janssen Biotech)	4
4	7	Palivizumab (Synagis; Astra Zeneca)	104
5	4	Asparaginase (Erwinaze; Jazz Pharmaceuticals)	153
6	--	Defibrotide sodium (Defitelio; Jazz Pharmaceuticals)	138
7	8	Pneumococcal 13-valent conjugate vaccine (Prevnar-13; Pfizer)	19
8	5	Eculizumab (Soliris; Alexion)	15
9	10	Pegfilgrastim (Neulasta; Amgen)	10
10	9	Dornase alfa (Pulmozyme; Genentech)	92

<sup>a</sup> 340B purchases were excluded from the analysis.

<sup>b</sup> May 2019 through April 2020.

<sup>c</sup> Ranking from January 2020 Drug Price Forecast based on data for September 2018 through August 2019.

Abbreviation: GPO = group purchasing organization.



by Genentech and market experts, while in the CAR-T platform, tisagenlecleucel's indication-based price of \$475,000 has stayed the same.<sup>11</sup> Voretigene neparvovec, a gene replacement therapy for RPE65-mediated inherited retinal dystrophy — which can cause complete blindness<sup>12</sup> — continues to be priced at a total of \$850,000 for treatment of both eyes.<sup>13</sup> The costs of these novel agents continue to impact implementation and require a multidisciplinary team to analyze handling and delivery, as well as the financial impact to the overall hospital budget.

## In the pipeline

The investigational pipeline in pediatrics continues to focus on treatment of rare diseases using monoclonal antibodies, gene therapy and orphan drugs.

As in other areas, the impact of COVID-19 on the pediatric pharmaceutical pipeline is mostly seen in the delay and suspension of trials and research of potential medications. Bluebird bio released a statement that the biologics license application (BLA) for LentiGlobin gene therapy for  $\beta$ -thalassemia will be delayed by COVID-19 into mid-2021. Thus, bluebird bio may broaden the patient population to include  $\beta^0/\beta^0$  genotypes and pediatric patients.<sup>14</sup>

Moderna Therapeutics creates messenger ribonucleic acid medicinal therapy for a wide range of rare diseases. It has halted its pediatric respiratory trials focusing on respiratory syncytial virus from entering phase 2 trials, as well as phase 1/phase 1b trials researching treatments for phenylketonuria and glycogen storage disorders (type 1a, G6Pase).<sup>15</sup>

A gene therapy trial for the treatment of Duchenne muscular dystrophy (DMD), a genetic degenerative disease that leads to progressive weakness of muscles, stopped enrolling human subjects in the phase 3 trial for SRP-9001, micro-dystrophin. The goal of this therapy is to evaluate the safety and efficacy of exogenous gene transfer in DMD patients.<sup>16</sup>

A clinical hold was put on AAVance phase 2/3 trial with LYS-SAF302 for patients with mucopolysaccharidosis type IIIA. As of June 2020, 19 out of 20 patients had been treated and all patients will continue to be monitored. LYS-SAF302 is an intracerebral administration of gene therapy that showed localized findings on magnetic resonance images at the injection sites.<sup>17</sup>

Table 10 lists additional products currently in development that, in some cases, are expected to have substantial costs associated with their use.

**Table 10. Important late-phase investigational drugs with pediatric studies ongoing**

Disease state/condition	Drug	Clinical trial phase	Manufacturer
$\beta$ -thalassemia	LentiGlobin	3	Bluebird Bio
Cutaneous T-cell lymphoma	SGX301	3	Soligenix
Crohn's disease	SGX203	3	Soligenix
Inflammatory bowel/Crohn's disease	Alicaforsen	3	Atlantic Healthcare
Mucopolysaccharidosis (IIIA)	LYS-SAF302	3	Lysogene
Duchenne muscular dystrophy	SRP-9001	2	Sarepta Therapeutics
Sickle cell disease	LentiGlobin (BB305)	2	Bluebird Bio
Respiratory syncytial virus	mRNA-1172, -1777, -1345	1/2	Moderna
Congenital disorders of glycosylation	CERC-801, -802, -803	2 1	Cerecor
Spinal muscular atrophy	LM1070	2	Novartis
	RG7916	2	Roche/Genentech/PTC Therapeutics/Spinal Muscular Atrophy Foundation
	CK-2127107	2	Cytokinetics/Astellas
	Zolgensma IT	1/2	AveXis

Data derived from Biospace, *The Journal of Allergy and Clinical Immunology*, ClinicalTrials.gov, Cure SMA and *Pediatric Neurology*.<sup>17-21</sup>

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## Key therapeutic class summaries

# Oncology

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3.63%

Period projected  
inflation rate

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23.69%

Portion of drug spend

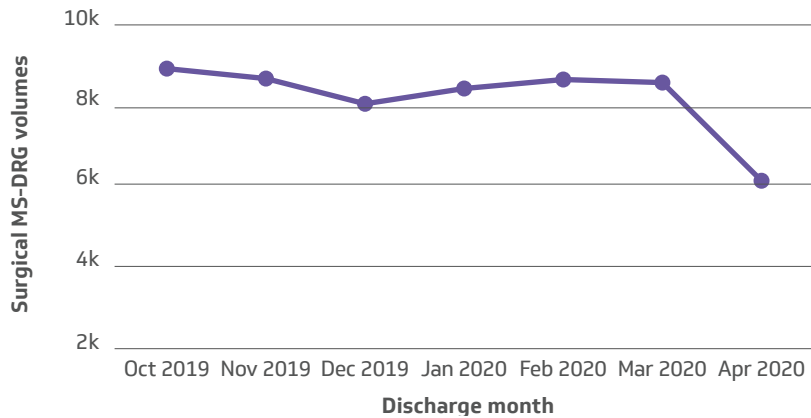
While many service lines have been disrupted due to COVID-19, oncology has retained some of its resiliency. At the height of the pandemic, ambulatory infusion centers were reporting an average decrease in new patient visits by 24%, infusion volume by 7% and radiology about 10%, with return patient visits decreasing by approximately 30%. During this time ambulatory infusion centers remained open — albeit with precautions in place — to continue their mission of providing life-sustaining therapy to cancer patients receiving treatment.

### Short- and long-term effects of COVID-19 on oncology patients

The extent of the impact of COVID-19 on the oncology space will be difficult to measure, especially when considering the vast disruptions to patient care spanning acute treatments and the long-term effects of delaying treatment, preventative measures and clinical trials. During the crisis many programs redirected their staff to accommodate the influx of acute care patients. Some of the programs affected included those that provided community outreach and cancer screenings. Clinical trial recruitment swiftly halted and many clinical trials currently under way were placed on hold. Additionally, a steep decline in preventative services was noted as patients refrained from visiting primary care physicians. A recent IQVIA report titled “Shifts in Healthcare Demand, Delivery, and Care During the COVID-19 Era,” states that the number of mammograms, colonoscopies and pap smears have declined by 87%, 90% and 83%, respectively, since February.<sup>1</sup> It is estimated that a continued reduction in screenings through June could lead to more than 80,000 delayed cancer diagnoses, which may result in later stage cancer diagnoses for many patients. Moreover, the temporary closure of surgery centers may have a long-lasting effect on cancer patients’ outcomes due to the lack of biopsies and tumor removal surgeries being performed, as well as chemotherapy treatments being postponed.

The Vizient Clinical Data Base reviewed member data to compare inpatient and non-inpatient volumes between October 2019 to April 2020. **Findings** illustrate a decline in both surgical and medical inpatient oncology volumes of approximately 36% and 26%, respectively, during this time frame. The top five Vizient oncology sub-service lines with the largest percentage decline in surgical volumes were genitourinary (42%); gynecologic (40%); thoracic (37%); gastroenterology (34%); and ear, nose and throat/oral (22%) (Figure 1). The top five oncology sub-service lines with the largest percentage decline in medical volumes were other/unspecified (30%), thoracic (29%), gastroenerology (26%), lymphoma (25%) and leukemia (18%) (Figure 2).

**Figure 1. Inpatient oncology surgical MS-DRG and sub-service line volume changes<sup>a,b</sup>**



Top five Vizient sub-service lines with surgical MS-DRG volumes	Case volume decline, %
Oncology-gastroenterology	-33.9
Oncology-genitourinary	-42.1
Oncology-thoracic	-36.5
Oncology-gynecologic	-40.1
Oncology-ENT/oral	-21.7

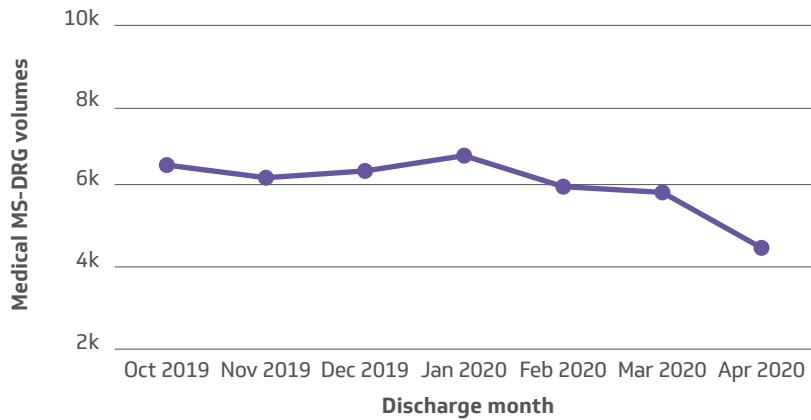
Vizient CDB data for October 2019 to April 2020; inpatient, n = 208 hospitals.

<sup>a</sup> Includes patients ≥ 18 years of age.

<sup>b</sup> Vizient service line: oncology (principal diagnosis: C000-C969Z, D000-D09Z, D45-D47Z, J910, R180, Z510-Z511Z, Z850-Z85Z, Z86002-Z86007, Z08 and Z421), surgical MS-DRGs

Abbreviations: CDB = Clinical Data Base; ENT = ear, nose and throat; MS-DRG = Medicare severity-diagnosis related group.

**Figure 2. Inpatient oncology medical MS-DRG and sub-service line volume changes<sup>a,b</sup>**



Top five Vizient sub-service lines with medical MS-DRG volumes	Case volume decline, %
Oncology-gastroenterology	-25.7
Oncology-leukemia	-17.6
Oncology-other/unspecified	-30.2
Oncology-lymphoma	-24.9
Oncology-thoracic	-29.4

Vizient CDB data for October 2019 to April 2020; inpatient, n = 208 hospitals.

<sup>a</sup> Includes patients ≥ 18 years of age.

<sup>b</sup> Vizient service line: oncology (principal diagnosis: C000-C969Z, D000-D09Z, D45-D47Z, J910, R180, Z510-Z511Z, Z850-Z85Z, Z86002-Z86007, Z08 and Z421), medical MS-DRGs

Abbreviations: CDB = Clinical Data Base; MS-DRG = Medicare severity-diagnosis related group.

## Practice changes

As service lines quickly learned to adapt to online platforms, oncology clinics ramped up their telehealth services to remain connected to a particularly vulnerable patient population. The IQVIA report noted that 23% of interactions are occurring via telehealth to enable patients not being actively treated or in need of a

physical assessment to remain at home.<sup>1</sup> Additional practice changes have also been implemented, including transitioning to oral therapy, converting to chemotherapy regimens with longer intervals between treatments, and using subcutaneous administrations and self-injections (devices) where applicable.

## Regulations

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security (CARES) Act was enacted to expand health care providers' funding and reduce lost revenue during the COVID-19 pandemic.<sup>2</sup> The CARES Act includes the elimination of the Medicare sequestration from May 1 through Dec. 31, 2020, the ability to request accelerated payments for inpatient services, increased Medicaid financing, and expanded Medicare telehealth flexibilities that include distant sites and hospice recertification. Moreover, the act includes multiple changes to the provision of home-based care services, such as billing processes, physician contracts, remote monitoring and coverage determinations. Third-party payers have also loosened their restrictions on site of care and prior authorizations for treatment.

## Budget impact

As mentioned above, oncology chemotherapy infusion centers experienced a 7% average decline in infusion visits. Table 11 shows the changes in Vizient member antineoplastic spend and quantity sold from January through April 2019 versus the same time period in 2020, overlapping the greatest point of inflection due to COVID-19 to date. During this time period the category experienced a 1.2% change in quantity of units purchased but an 18.4% change in drug spend.

**Table 11. Change in spend and quantity for subcategories of oncology drugs**

Drug subcategory	Change in spend, %	Change in quantity sold, %
Antibody/antibody-drug complexes	81	106.1
Miscellaneous antineoplastic targeted therapy	84.8	56.9
Isocitrate dehydrogenase inhibitors	56.4	52.3
Bispecific T-cell engagers	56.7	52.1
Tyrosine kinase inhibitors	45.7	38.9
Antineoplastic combinations	-25.2	-30.3
Immunotoxins	-23.1	-18.4
Antibiotics	-23.8	-1.9
HER2 antibodies	9.1	-12.3
Metal complexes	-10.6	12.7
Alkylating agents	-4.8	4.6

Based on the Vizient global Price, Quantity and Mix report, June 2020.

The subcategory with the highest change in quantity sold and price was antibody/antibody-drug complexes, which includes antibody-drug conjugates and immunotoxins such as ado-trastuzumab emtansine, brentuximab vedotin, inotuzumab ozogamicin and gemtuzumab ozogamicin. The immunotoxin pharmaceutical agent moxetumomab pasudotox-tdfk experienced a decrease in spend and quantity sold during this same time frame.

Two subcategories with the largest decline in spend and quantity sold was the antineoplastic combinations and immunotoxins. These combination products included ribociclib succinate/letrozole and daunorubicin/cytarabine liposomal, along with the CD123-directed cytotoxin tagraxofusp-erzs. Additionally, the volume of oncology infusion center services between April 2019 and April 2020 declined by approximately 33% when measuring billing for chemotherapy infusion services, and an average decline of 40% was seen for the top 10 oncology drugs.<sup>3</sup>

The highest-ranking oncology products by spend for Vizient members from May 2019 to April 2020 can be found in Table 12. Also included is the change in spend from January through April 2019 versus the same time period in 2020. This list has changed significantly over the past couple of years due to the approval of immunotherapy and its impact on treatments across many different cancer types. COVID-19 has had a profound effect on chemotherapy infusion clinics.

**Table 12. Top 10 oncology drugs by spend among Vizient members**

Rank	Drug	Change in spend, %
1	Pembrolizumab	51.9
2	Rituximab	-12.3
3	Nivolumab	-5.3
4	Bevacizumab	-11.7
5	Trastuzumab	-22.6
6	Pemetrexed disodium	7.6
7	Daratumumab	43.9
8	Pertuzumab	21.2
9	Atezolizumab	71.6
10	Ibrutinib	38.3

Based on the Vizient global Price, Quantity and Mix report, June 2020.

Tocilizumab, an oncology rescue agent, is being used in the fight against COVID-19. Tocilizumab is an interleukin 6 (IL-6) inhibitor originally approved for the treatment of moderate to severe rheumatoid arthritis (RA). It has since received approval from the FDA to be used to treat CAR T-cell-induced cytokine release syndrome,<sup>4</sup> as early data suggested patients with severe symptoms were experiencing a high expression of IL-6 in combination with mild-to-severe cytokine storms. There has been a significant increase in spend for this drug — over 213% — when comparing January to April 2019 with the same time period in 2020.

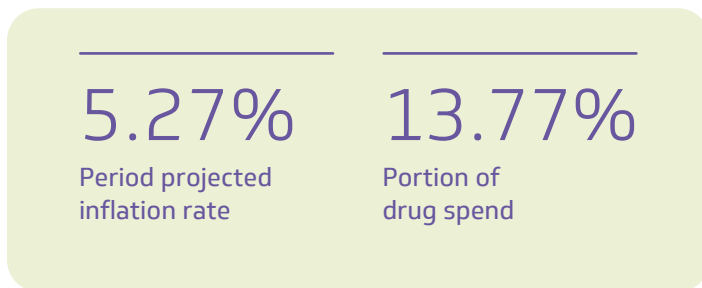
Today, the number of in-person patient visits has nearly returned to normal, with only 9% to 10% of visits still conducted virtually. New referrals from primary care physicians and other specialties remain below baseline. Patients with rapidly progressing tumors such as pancreatic, head and neck cancer, and lung cancer have higher referral rates than those with solid tumors that

progress more slowly, while patients with hematologic conditions in which blood work is screened have the lowest referral rates.<sup>1</sup>

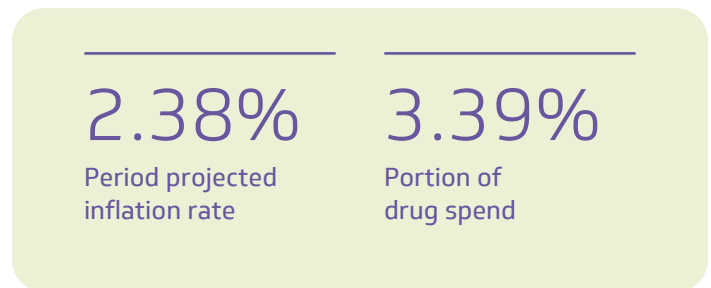
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## Disease-modifying antirheumatic agents and immunomodulators

### Disease-modifying antirheumatic agents



### Immunomodulators – multiple sclerosis



### A closer look

The estimated annual cost to treat MS in the U.S. is \$28 billion.<sup>1</sup> Disease-modifying therapies (DMTs) account for 63% of overall health care costs and 75% of MS-related health care expenditures.<sup>2,3</sup> The annual cost of therapy has risen remarkably since first-generation DMTs were launched in the mid-1990s. Despite generic introductions, costs continue to rise as additional treatments are

approved. The blockbuster drug ocrelizumab (Ocrevus; Genentech), a CD20-directed cytolytic antibody indicated for the treatment of relapsing or primary progressive MS, had the highest total immunomodulator class sales among Vizient members from May 2019 through April 2020 (Table 13).



**Table 13. Top immunomodulators by spend among Vizient members**

Drug	Percentage of total sales
Ocrelizumab (Ocrevus)	41.1
Natalizumab (Tysabri)	11.8
Fingolimod (Gilenya)	11.7
Dimethyl fumarate (Tecfidera)	10.6
Glatiramer acetate (Copaxone)	7.6
Interferon beta-1a (Avonex)	7.1
Interferon beta-1a/albumin human (Rebif)	5.1
Interferon beta-1b (Betaseron)	2.2
Glatiramer acetate (glatiramer acetate)	2
Peginterferon beta-1a (Plegridy)	0.8

Vizient member data for May 2019 through April 2020.

Price increases for specialty biologics do not only affect patients with MS: Disease-modifying anti-rheumatic drugs (DMARDs) used to treat RA are among the most expensive drugs in the U.S. Price fluctuations for six of the most common DMARDs were analyzed from 2010 through 2019, with a mean increase of 160% noted for each drug during this time period.<sup>4</sup> In January 2020, the list price of Abbvie’s adalimumab increased by 7.4%,<sup>5</sup> with Pfizer also increasing its list prices of over 40 products by

more than 9%, including tofacitinib (Xeljanz; Pfizer).<sup>6,7</sup> As shown in Figure 3, infliximab (Remicade; Janssen) had the largest market share among the DMARDs based on Vizient member spend between May 2019 through April 2020. The Remicade biosimilars — infliximab-dyyb (Inflectra; Pfizer) and infliximab-abda (Renflexis; Merck) — are starting to gain market share within the class.

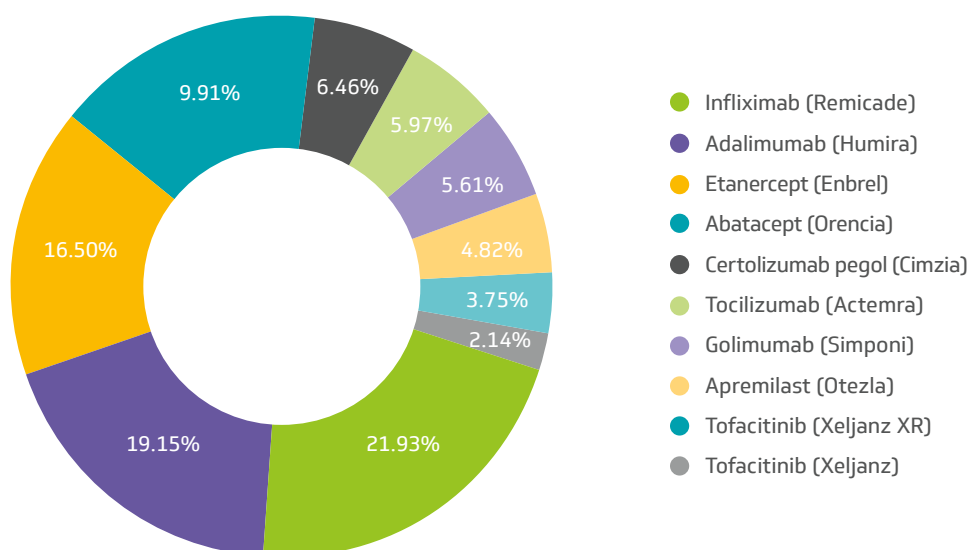
### Oral formulations new to the MS market

There has been rapid growth in oral formulations in the MS market. In 2019, once-daily siponimod tablets (Mayzent; Novartis) were approved for relapsing forms of MS, including relapsing-remitting MS (RRMS), secondary-progressive MS (SPMS) and clinically isolated syndrome (CIS). Siponimod was the first oral treatment specifically formulated for people with active SPMS, and the price was set at \$88,500 per year.<sup>8</sup>

Cladribine tablets (Mavenclad; EMD Serono) were also approved for adults with relapsing forms of MS, but not for CIS. Cladribine is the first short-course oral therapy for relapsing forms of MS. Weight-based therapy can cost as much as \$99,500 per year, or \$199,000 for the two-year course of treatment.<sup>9</sup>

Due to its probable mechanism of action, cladribine, as well as several other DMTs, were included in the United Kingdom’s MS Trust and the Italian Society of Neurology’s COVID-19 guidelines with a recommendation to suspend or not initiate treatment, as they may make patients more susceptible to COVID-19.<sup>9</sup> The National MS Society’s National Medical Advisory Committee’s guidelines recommend that therapy should be provider-directed

**Figure 3. Top disease-modifying therapies by market share among Vizient members**



Based on Vizient member data for May 2019 through April 2020.

and individualized. Overall, most MS patients will benefit more from continuing their MS treatments rather than discontinuing them due to COVID-19 concerns.

Diroximel fumarate delayed-release capsules (Vumerity; Biogen) were approved in October 2019 for the treatment of relapsing forms of MS, including CIS, RRMS and SPMS. The inactive prodrug rapidly converts to monomethyl fumarate — the same active metabolite of dimethyl fumarate (Tecfidera; Biogen) — in the body. However, diroximel fumarate is associated with lower rates of gastrointestinal adverse events than dimethyl fumarate. Diroximel fumarate's launch price is set at \$88,000 per year of treatment.<sup>10</sup>

On March 25, 2020, the sphingosine-1-phosphate (S1P) receptor modulator ozanimod (Zeposia; Celgene/Bristol Myers Squibb) was approved to treat CIS, SPMS and RRMS in adults. Ozanimod does not require genetic testing and is the first and only S1P receptor modulator that does not require first-dose observation. Due to COVID-19 restrictions,

ozanimod didn't launch until June 1, with an annual cost of therapy of approximately \$86,000, which is lower than the cost of its oral competitors' annual treatment.<sup>11</sup>

## RA market growing slowly

The RA market did not grow as rapidly as the MS oral market, and in the last year, only one new molecule entered the space. In August 2019, upadacitinib (Rinvoq; AbbVie) was approved for the treatment of adults with moderately to severely active RA who have had an inadequate response or intolerance to methotrexate. Upadacitinib is a once-daily oral Janus kinase (JAK) inhibitor with an annual cost of \$59,000.<sup>12</sup>

Injectable formulations new in this market are methotrexate (RediTrex; Cumberland), a preservative-free, single-dose prefilled syringe and rituximab-abbs, another competitor in the **biosimilars** space. Methotrexate is a once-weekly subcutaneous injection indicated for patients with severe, active RA who are intolerant of or have had an inadequate response to first-line therapy.

# Treatments for RA during COVID-19

The American College of Rheumatology has published guidance for the treatment of adult patients with RA during the COVID-19 pandemic. The guidelines advise managing patients per the usual standard of care; if a patient has been exposed to or has COVID-19 (documented or presumed), then medication adjustments are recommended.<sup>13</sup>

Many RA therapies are being investigated for the treatment of COVID-19. Widespread shortages of hydroxychloroquine sulfate were experienced due to increased demand, despite a lack of supporting evidence and potential adverse effects. Because the shortage made hydroxychloroquine difficult to obtain for RA patients, the FDA quickly approved Abbreviated New Drug Applications from manufacturers to allow the temporary compounding of hydroxychloroquine formulations from APIs by pharmacies and outsourcing facilities. However, due to global demand, the price of hydroxychloroquine APIs rose 350%.<sup>14</sup>

The National Institute of Allergy and Infectious Diseases has launched a trial in which hospitalized COVID-19 patients are treated with remdesivir (Gilead) and baricitinib (Olumiant; Eli Lilly and Company/Incyte). Baricitinib is a JAK inhibitor indicated for the treatment of adult patients with moderately to severely active RA who have had an inadequate response to one or more tumor necrosis factor

(TNF) antagonist therapies. It is also being investigated as a monotherapy for the prevention of cytokine storm associated with COVID-19.

Trials of tocilizumab (Actemra; Roche) in combination with remdesivir in hospitalized patients with severe COVID-19 pneumonia have also been initiated. Tocilizumab is an IL-6 receptor antagonist indicated for the treatment of adult patients with moderate to severe RA who have had an inadequate response to one or more DMARDs. It is theorized that IL-6 inhibitors counter the overreaction of the immune system. Sales of tocilizumab rose 30% in the first quarter of 2020 compared to the same time period in 2019.<sup>15</sup>

Sarilumab (Kevzara; Regeneron/Sanofi) is another IL-6 inhibitor used for RA that is being studied as a potential treatment for COVID-19, while the RA investigational drug otilimab (GSK 3196165; GlaxoSmithKline), an anti-granulocyte macrophage colony-stimulating factor, is under investigation for treating pneumonia caused by COVID-19. TNF inhibitors — which are used to decrease inflammation in RA patients — are also being considered for the treatment of COVID-19 patients who develop acute respiratory distress syndrome.

## What's next

The MS and RA markets will be driven by the entry of lower-cost generics and biosimilars and the approval of new agents that have the potential to significantly increase health system drug expenditures.

- The FDA has accepted, with Priority Review, the supplemental BLA for ofatumumab (Arzerra SubQ; Novartis), a CD20-directed cytolytic monoclonal antibody used to treat relapsing forms of MS in adults. If approved in September 2020, it will be a self-administered once-monthly subcutaneous injection. It is currently marketed for the treatment of chronic lymphocytic leukemia via intravenous infusion.
- Ponesimod (ACT-128800; Janssen) is an investigational selective sphingosine-1-phosphate receptor 1 modulator for the treatment of relapsing MS. Phase 3 Oral Ponesimod Versus Teriflunimide In Relapsing Multiple Sclerosis (OPTIMUM) trial results found an improvement in fatigue-related symptoms, potentially positioning ponesimod as a choice for patients seeking a more targeted treatment option. An approval decision should be made during the first quarter of 2021.
- Vitalis has three combination products that have received orphan drug destination for the treatment of RRMS patients who experience fumarate flush. The company's proprietary VTS-Aspirin platform is being evaluated for use with dimethyl fumarate, diroximel fumarate and monomethyl fumarate. In April 2020, the FDA approved monomethyl fumarate delayed-release oral capsules (Bafiertam; Banner Life Sciences) to treat relapsing forms of MS. Monomethyl fumarate is the bioequivalent alternative to dimethyl fumarate submitted under the 505(b)(2) filing pathway; its launch and pricing are pending.
- Filgotinib (Glp0634; Galapagos/Gilead) is an investigational oral selective JAK1 inhibitor under Priority Review by the FDA for the treatment of moderate to severe RA in adult patients.

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# Plasma critical care products: IgIV and albumin

2.83%

Period projected  
inflation rate

4.21%

Portion of drug spend

Supply of intravenous immunoglobulin (IgIV) began stabilizing during the last half of 2019 and into the first half of 2020, which was reflected in the reduced increase in the volume-weighted average price. Ig pricing is expected to continue to modestly increase over the next 18 months. Albumin pricing continues to remain stable, as product supply is not anticipated to have significant fluctuations.

Interest in plasma-derived therapies for COVID-19 patients has spiked, and providers continue to assess utilization of convalescent plasma in addition to off-label Ig therapy for affected patients. Additionally, plasma manufacturers have initiated international research partnerships to examine the potential of future plasma-derived therapies to treat SARS-CoV-2. Due to the global economic impact of COVID-19, which has affected sourcing and the supply chain across all levels, reduced plasma donations and subsequent manufacturing supply are estimated to impact the market in 2021. Investigational findings around plasma-derived pharmaceuticals and results of clinical trials will also have an impact on future supply outlook and pricing.

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## Hot topic: Responding to a global pandemic

# Infectious disease and the management of COVID-19

3.16%

Period projected  
inflation rate

11.36%

Portion of drug spend

It is important to recognize that significant advancements in the prescribing and use of infectious disease treatments continue to occur in addition to those directed at the COVID-19 virus. For example, highly anticipated consensus guidelines for vancomycin dosing and monitoring were published in March 2020, significantly advancing the recommended approach to the management of methicillin-resistant *Staphylococcus aureus*. Vizient hosted a continuing education webinar to help members understand and implement these new recommendations. In addition, our research yielded new insights about patients with presumed penicillin allergies: The Vizient Pharmacy Network Antimicrobial Stewardship Committee evaluated a dataset of nearly 11,000 inpatients and found that physicians unnecessarily prescribe inferior antibiotics due to documented, but unconfirmed, penicillin allergies. During this time of extreme concern about health care costs and medication safety, inappropriate prescribing patterns are an essential area of focus for improvement. Therefore, Vizient and its members continue to make advancements in the appropriate use of anti-infectives in numerous situations. Still, the breadth and depth of COVID-19 is currently top of mind for clinicians.

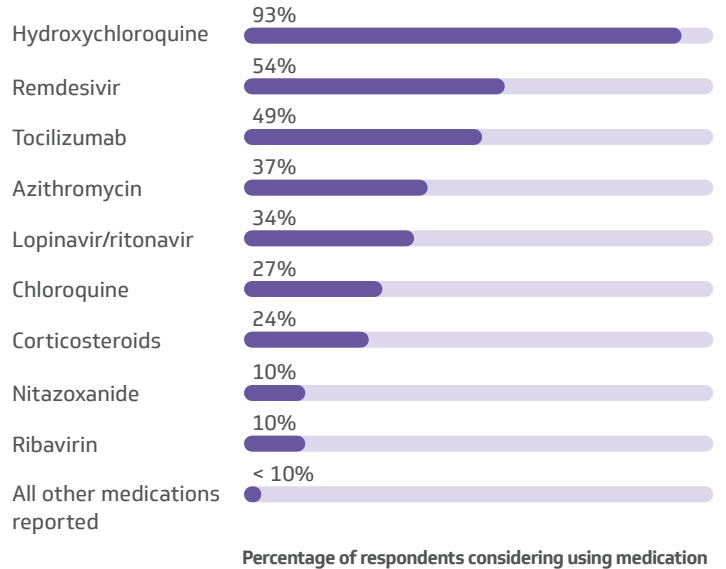
A critical element of support for our members during this crisis has been to stabilize and expand the supply and availability of medications needed to treat the increasing number of critically ill patients. At the same time, Vizient has been working to expand access to relevant and timely clinical insight related to pharmaceutical interventions. Given the scope and expertise of the Vizient membership, one of our priorities was to survey members about the treatment options being used during the initial COVID-19 surge.

## Vizient pharmacotherapy survey results

Pharmacotherapy for COVID-19 is a rapidly evolving space. A [survey](#) of Vizient members conducted from March 23–April 5, 2020, gathered practice insights on medications and dosing that hospital organizations were using to treat critically ill COVID-19 patients. Clinical practice in the treatment of COVID-19 has evolved since the distribution of this survey. For example, the survey demonstrated that 93% of members were considering the use of hydroxychloroquine to manage patients at that time (Figure 4). Currently, most major guidelines caution against hydroxychloroquine use unless it’s within the confines of a clinical trial. In addition, the FDA has revoked the hydroxychloroquine Emergency Use Authorization (EUA). Member survey results revealed that 54% were considering the use of remdesivir, with 49% looking at tocilizumab. Members’ approach to tocilizumab dosing was highly variable, with regimens split relatively evenly between fixed and weight-based dosing.

As shown in Figure 5, hydroxychloroquine demand peaked in late March through early April and has decreased since that time. Similarly, demand for azithromycin (oral and intravenous) surged toward the end of March (Figures 6 and 7), coinciding with initial limited reports from France describing the use of hydroxychloroquine and azithromycin combination therapy.<sup>1</sup> Figure 8 demonstrates that peak demand for tocilizumab occurred around the beginning of April and has tapered off as most national organizations recommend use within a clinical trial setting.

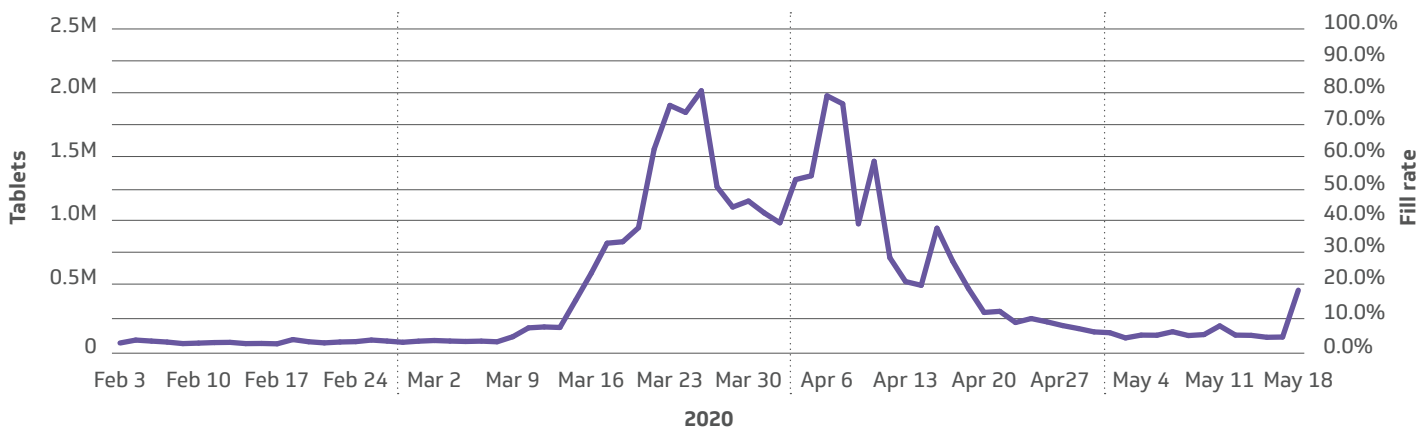
**Figure 4. Top-ranking medications considered early on for management of COVID-19 patients<sup>a</sup>**



<sup>a</sup> Depending on patient presentation.

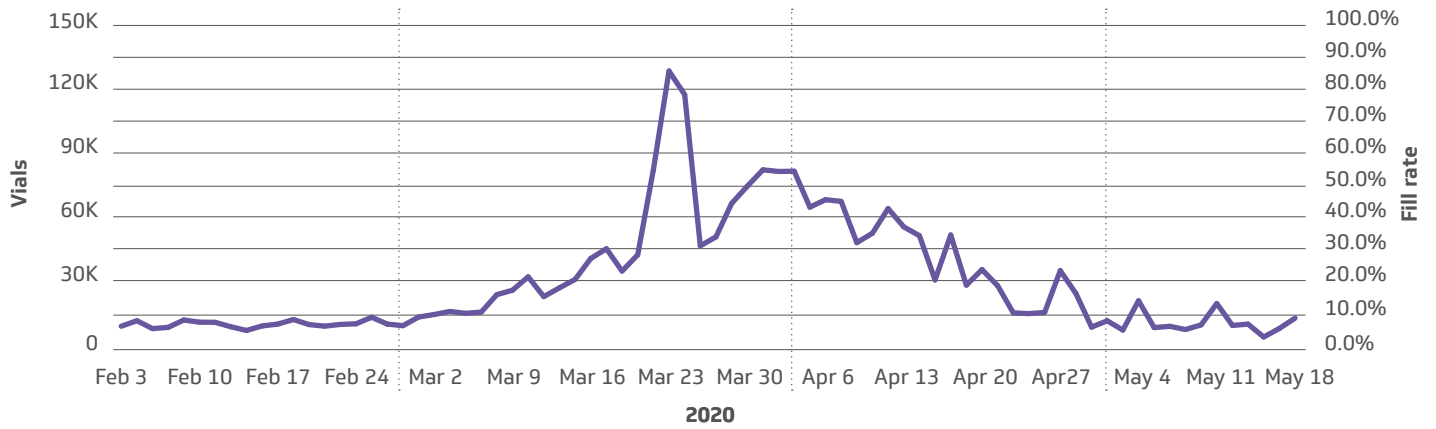
Note: Medications with no reports included baricitinib, ganciclovir, interferon alfa-2b and doxycycline.

**Figure 5. Demand for hydroxychloroquine among Vizient members, February through May 2020**

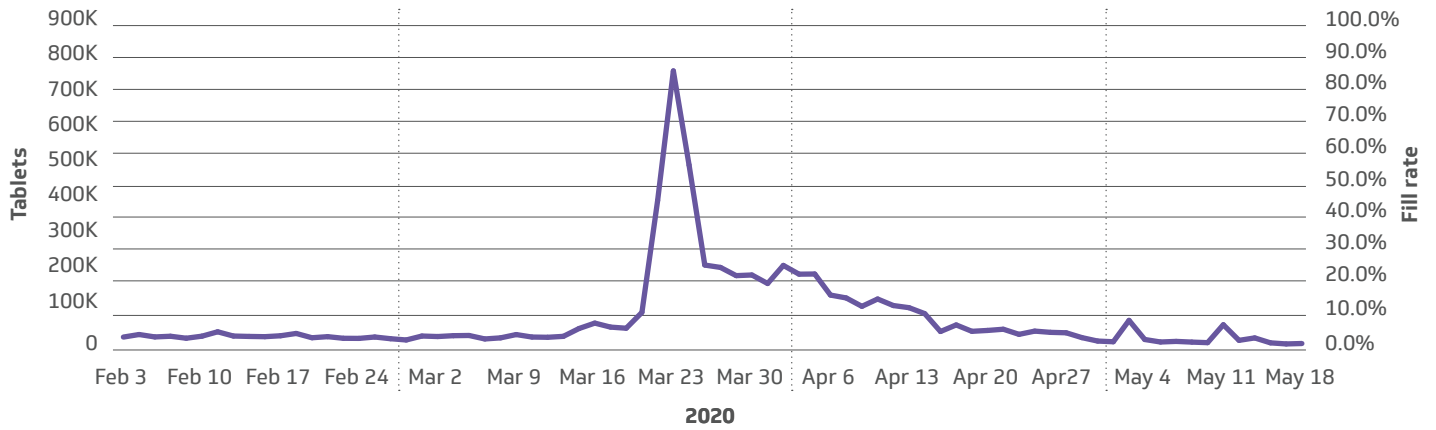




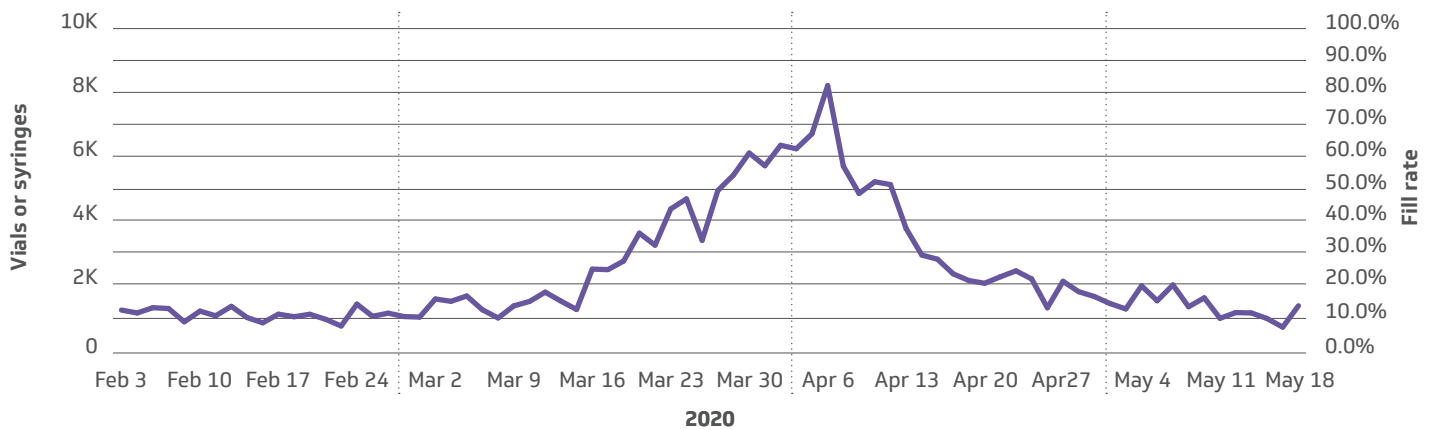
**Figure 6. Demand for intravenous azithromycin among Vizient members, February through May 2020**



**Figure 7. Demand for oral azithromycin among Vizient members, February through May 2020**



**Figure 8. Demand for tocilizumab among Vizient members, February through May 2020**



## Potential treatments and vaccines

Multiple new molecular entities (NMEs) and medications currently approved for other indications are being studied for the treatment of SARS-CoV-2 infection and complications of COVID-19 in the U.S. Over 200 interventional COVID-19 clinical trials are recruiting or enrolling patients according to [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Existing therapeutic modalities approved for other indications to watch in this space include anakinra, baricitinib, eculizumab, emapalumab-lzsg, ravulizumab-cwvz, ruxolitinib phosphate and sarilumab.<sup>2</sup> NMEs or agents not yet FDA approved for other indications of interest include dociparstat sodium, lenzilumab, leronlimab, olokizumab, remdesivir, remestemcel-L and tradipitant.<sup>2</sup> Through the FDA EUA,<sup>3</sup> remdesivir is available via limited compassionate use (e.g., pregnant women), expanded access and clinical trials. The U.S. Department of Health and Human Services recently announced that more than 500,000 courses of remdesivir therapy will be distributed between July and September of this year.<sup>4</sup> Pricing has been set at \$3,120 per five-day course (six vials) for private insurance companies, and \$2,340 per course for the United States Department of Veterans Affairs system.<sup>5</sup> Additional [details](#) are available on the Vizient website.

Successes in reducing SARS-CoV-2 infection rates pose ironic challenges for vaccine trial execution,<sup>6</sup> and future barriers will include ensuring production scalability and coordinating widespread administration once a viable vaccine is identified.<sup>6</sup> More than 100 vaccines targeting SARS-CoV-2 are in various stages of development worldwide,<sup>2</sup> and vaccine candidates could enter phase 3 trials as early as July of 2020.<sup>7</sup> Once a vaccine is available, the CDC will implement its Pandemic Vaccine Distribution Plan, which was used during the 2008-2009 H1N1 pandemic, and leverage the Vaccines for Children (VFC) platform for distribution.<sup>8</sup>

## Resources for ongoing disaster preparedness and response

Continuing to plan and prepare for COVID-19 — both in terms of managing the disease and helping hospital leaders implement strategies — will continue to be a major focus for Vizient members. COVID-19 resources to support ongoing management and recovery are provided on the Vizient member [disaster preparedness page](#). These tools have been generated through rich collaboration with Vizient members as well as internal subject matter expertise. Other Vizient resources include:

- **Pharmacotherapy for COVID-19: Evidence Summary** — First published in late March of 2020, this publication continues to be updated regularly to provide the most relevant, up-to-date information on literature surrounding COVID-19 management.
- **The Management of Inhaled Medications During the COVID-19 Pandemic** — Early in the pandemic, it was advised that aerosol-generating procedures should be avoided to control infections in the patient care setting. This Vizient white paper supports member decision-making in this arena.
- **The effect of COVID-19 PPE supply shortages on USP compliance: recommendations for management** — A heightened demand for PPE due to COVID-19 led Vizient to publish this article, which is updated regularly.
- **Pharmacy practice considerations** — To share member experiences with COVID-19 and the recommendations of national organizations, Vizient produced this wide-ranging list in early April 2020. Members can use this resource to develop pandemic response plans. Member-specific supportive tools are also available.
- **Ventilation Medication Demand Projection Calculator** — Organizations experiencing or anticipating COVID-19 patient surges can use this calculator to estimate needs for additional demand based on patient population. Since inception, member adoption of this tool has been significant.
- **Drug mitigation strategies** — The increased utilization of ventilator medications has led to various medication shortages. Drug mitigation strategies are compiled from Vizient Clinical Pharmacy Council members and reviewed by internal subject matter experts to help with ongoing drug shortages. Additional mitigation strategies have been created for intravenous analgesic and sedation agents.
- **Field hospital toolkit** — The potential need for alternative care sites was recognized early in the COVID-19 pandemic. In addition to offering members assistance in setting up a field hospital, Vizient has created this toolkit to support member activity.
- **Therapeutic controversies** — While not unexpected with a novel disease state process, a number of pharmacotherapeutic controversies have arisen in the management of COVID-19 patients; this document summarizes available evidence-based literature and presents information in a user-friendly question and answer format.

- **IV push medication reference** — Vizient has published this guide in response to member requests to conserve infusion pumps, nursing time, IV fluids and dosage form-specific drugs on shortage.
- **Disaster preparedness page** — The upcoming hurricane and influenza seasons will only add to the complexity, uncertainty and stressors of predicting COVID-19 resource demands. This webpage offers members support as they incorporate these complex variables into future planning.

## Infectious diseases' impact beyond COVID-19

The impact of COVID-19 has not been limited to pharmacotherapy in this disease state only. Comparing antimicrobial purchases in March and April 2019 to the same time period in 2020 brings some remarkable trends to light. For example, first-generation cephalosporin use fell by 4.4%, presumably because of decreased prophylactic use due to deferred elective operative procedures. Conversely, fourth-generation cephalosporin use increased by 39.3%, possibly related to an increased incidence of hospital-acquired pneumonia. The use of dalbavancin, a long-acting lipoglycopeptide, increased by 57.5% in this time period — perhaps pointing to clinician attempts to free inpatient health system resources for COVID-19 patients while at the same time prevent the risk of additional infections.

Concerns have been raised regarding patients, or parents of patients, deferring or skipping preventative care, including routine vaccinations.<sup>9</sup> This trend has been validated in a recent **report from the CDC** evaluating the effects of the pandemic on vaccine ordering and administration. The authors found a notable decrease in vaccine orders through the VFC program when comparing purchases from Jan. 7-April 21, 2019, to the same time frame in 2020.<sup>10</sup> The American Academy of Pediatrics has published guidance for ensuring the ongoing wellness and care of children during the COVID-19 pandemic<sup>11</sup> and has issued a statement responding to the CDC report.<sup>11</sup>

Additional information about missed and/or delayed vaccinations can be found in the **non-acute care** section of this forecast.

- 1 Gautret P, Lagier JC, Parola P, et al. Hydroxychloroquine and azithromycin as a treatment of COVID-19: results of an open-label non-randomized clinical trial. *Int J Antimicrob Agents*. 2020;105949. doi: 10.1016/j.ijantimicag.2020.105949
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- 11 The American Academy of Pediatrics. Guidance on providing pediatric well-care during COVID-19. The American Academy of Pediatrics. May 8, 2020. Accessed June 9, 2020. <https://services.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/clinical-guidance/guidance-on-providing-pediatric-well-care-during-covid-19/>

# Regulatory response to a global pandemic

In March 2020, the World Health Organization (WHO) declared COVID-19 a pandemic, associated with transmission of the novel coronavirus (2019-nCoV). The surge in hospitalized COVID-19 patients resulted in a spike in demand for drugs and supplies. Combined with a disruption in the supply chain, these market dynamics led to shortages, product allocations, and large price hikes of essential medications and PPE.

As shortages of N95 respirators, gowns, masks and shoe covers continue, pharmacies have undertaken inventory projection strategies, estimating the time remaining with existing inventory and establishing conservation programs. The FDA, United States Pharmacopeia (USP), National Institute for Occupational Safety and Health (NIOSH), CMS and DEA have provided guidance on a variety of issues, such as minimizing drug waste, implementing robust compounding standards, and establishing criteria for the use and reuse of PPE.

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*Certain regulatory requirements and expectations by the FDA, DEA, state health departments and accreditation agencies have been relaxed to allow greater attention to be focused on COVID-19 management.*

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## FDA

The FDA issued a final guidance, **Wholesale Distributor Verification Requirement for Saleable Returned Drug Product**, that announced a one-year enforcement discretion of a provision of the Drug Supply Chain Security Act (DSCSA) that would require wholesale distributors to verify the product identifier of saleable returned drugs before these products can be placed into inventory for resale. Although the requirement's initial effective date was Nov. 27, 2019, the enforcement delay was granted due to a lack of industry readiness, resources being directed to help manage COVID-19 and the need to avoid further supply chain disruptions stemming from an inability of wholesale distributors to meet the requirement.

## USP

The USP published **revised and new compounding standards** that became effective Dec. 1, 2019. The compounding process requires gowns, gloves and masks,

all of which are in short supply due to COVID-19. The following chapters received **appeals** and are currently being reviewed and revised:

- General Chapter <795> — Provides standards for compounding quality nonsterile preparations to reduce the risk of contamination, infection or incorrect dosing. Currently, the official version of this chapter is the 2014 revision.
- General Chapter <797> — Provides standards for the protection and safety of patients and health care workers — such as pharmacists, nurses, physicians and pharmacy technicians — involved in sterile compounding preparations. Currently, the official version of this chapter is the 2008 revision.
- General Chapter <825> — Provides standards for the preparation, compounding, dispensing and repackaging of sterile and nonsterile pharmaceuticals. When this chapter becomes official, it will be an **informational chapter**, unless otherwise required by a regulatory body.

Facilities that have already adopted these newly revised standards should work with their states, regulators and accreditation bodies to determine what additional actions may be required.

USP General Chapter <800>, which provides standards for safe handling of hazardous drugs to minimize the risk of exposure to health care workers, patients and the environment, was not subject to appeal and became effective Dec. 1, 2019. However, it remains **informational and not compendially applicable** until the revised Chapters <795> and <797> become official.

## NIOSH

NIOSH has released its List of **Hazardous Drugs in Healthcare Settings, 2020**, which is expected to become final in the last quarter of 2020. This list categorizes hazardous medications, which USP references in creating its compounding standards. The list will now have only two tables:

- Table 1 — Drugs that contain manufacturer's special handling information (MSHI) in the package insert and/or meet the NIOSH definition of a hazardous drug and are classified by the National Toxicology Program (NTP) as "known to be a human carcinogen," or classified by the International Agency for Research on Cancer (IARC) as "carcinogenic" or "probably carcinogenic."

- Table 2 — Drugs that meet the NIOSH definition of a hazardous drug, but do not have MSHI and are not classified by the NTP as “known to be a human carcinogen,” or by the IARC as “carcinogenic” or “probably carcinogenic.”

The [Procedures for Developing the NIOSH List of Hazardous Drugs in Healthcare Settings](#) formalizes the methodology that NIOSH uses to add hazardous drugs to its list, and describes the process for requesting drugs’ removal from or placement on the list. A third draft document, [Managing Hazardous Drug Exposures: Information for Healthcare Settings](#), is intended to help employers establish workplace-specific management procedures for hazardous drugs.

## CMS

CMS has issued new waivers and rules in response to the COVID-19 pandemic, including:

- Waiving requirements outlined in USP <797> to allow used face masks that have been removed and retained in the compounding area to be re-donned and reused during the same work shift in the compounding area only.
- Temporarily [expanded access](#) to telehealth services covered by Medicare to permit Medicare beneficiaries to receive care in their homes.

## DEA

The DEA has taken steps to facilitate appropriate patient care and help the nation respond effectively to the COVID-19 pandemic:

- DEA-registered hospitals and clinics have been granted the flexibility to use [satellite hospitals/clinics at nonregistered locations](#) and allow these satellite locations to receive shipments of controlled substances directly from distributors.

- DEA-registered practitioners can [distribute controlled substances](#) beyond 5% of the total number of dosage units of controlled substances distributed and dispensed during the same calendar year without being required to register as a distributor.
- A [decision tree](#) has been developed to help DEA-registered practitioners prescribe controlled substances without having to interact in-person with their patients.

In addition, to ensure that COVID-19 patients have access to an adequate and uninterrupted supply of medically necessary controlled substances, the DEA has:

- [Temporarily enabled](#) all DEA-registered bulk manufacturers to exceed the 65% ceiling in order to supply dosage form manufacturers with the APIs needed to provide Schedule II controlled substances.
- Issued a [final order](#) to increase the 2020 aggregate production quotas (APQ) by 15% for certain drugs needed to treat COVID-19; these include fentanyl, morphine, hydromorphone, codeine, ephedrine and pseudoephedrine, as well as certain essential controlled substance intermediates.

The DEA has also increased the APQ for methadone to ensure that opioid treatment programs have sufficient supplies to treat patients suffering from opioid use disorder.

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*State boards of pharmacy issued emergency orders and policies in response to COVID-19. The National Association of Boards of Pharmacy compiled and continues to regularly update this resource.*

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# Continued regulations in the era of COVID-19

The following regulatory guidances, enforcement discretions and temporary policies issued during the COVID-19 pandemic are intended for use only during the public health emergency. It is still to be determined when and how these actions will be halted and whether stricter standards will be mandated in the future.

## CMS

CMS released a [Frequently Asked Questions](#) document for state surveyors, health care facilities, patients, caregivers and accrediting organizations regarding the COVID-19-related suspension of certain nonemergency state survey inspections. Beginning in January 2021, the CMS will require accreditation for home infusion therapy services billed to Medicare. Currently eight organizations have deemed status as an accrediting organization of home infusion therapy suppliers.

## The Joint Commission

The [Joint Commission](#) has approved [changes](#) to its National Patient Safety Goals for all applicable accreditation programs; these changes are already effective. Revisions have also been made to Joint Commission standards related to medication titration orders; these [revisions](#) go into effect in September 2020 and January 2021.

## FDA

During the COVID-19 pandemic the FDA has clarified the following compounding policies for 503A pharmacies:

- The rule prohibiting the distribution of compounded preparations outside of a one-mile radius to health care facilities that are owned and controlled by the same entity that owns and controls the hospital or health system pharmacy is [draft guidance](#), and has not taken effect.

- The final guidance [Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act](#) was clarified to state that the FDA does not consider drugs that are on its [shortage list](#) or that have been discontinued and are no longer marketed as “commercially available.” In addition, the FDA does not consider a compounded drug produced by an outsourcing facility as “[essentially a copy](#)” if it is identical or nearly identical to an FDA-approved drug that is on its drug shortage list.

## International Organization for Standardization

To prevent drug delivery errors due to tubing misconnections, the International Organization for Standardization (ISO) developed the ISO 80369 series of small-bore connectors for various clinical applications. The FDA, CMS and Joint Commission all strongly encourage [transitioning](#) to these devices to minimize the risk of patient injury or death.

The first available compliant devices were the ISO 80360-3 small-bore connectors, commonly known as ENFit. To encourage adoption, legacy (non-ENFit) feeding tubes and cross-application adaptors are no longer manufactured, and after Jan. 1, 2021, transition sets and adaptors sold separately will no longer be manufactured. However, due to the COVID-19 pandemic, the Global Enteral Device Supplier Association will continue to support institutions that have already converted to ENFit products as well as those that have postponed its conversion with legacy products.

## EPA

The COVID-19 pandemic may also delay state adoption of the EPA final rule [Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine](#). This rule states that over-the-counter nicotine replacement therapies will no longer be considered hazardous waste when discarded and prohibits the drain disposal (i.e., flushing, sewerage) of hazardous waste pharmaceuticals at health care facilities.

# Where the rubber meets the road: The practice of evidence-based medicine during a pandemic

In 1992, physicians working at McMaster University in Hamilton, Ontario coined the term “evidence-based medicine” (EBM) to describe a new paradigm for medical practice and education that emphasized the use of medical literature to more effectively guide treatment decisions.<sup>1</sup> In the almost three decades since its introduction, EBM and evidence-based clinical guidelines have become the gold standard of high-quality patient care. No event in the recent past has jeopardized the current EBM paradigm. However, for many practitioners, the commitment to require proof of evidence before using a therapy was tested in mid-March when transmission of SARS-CoV-2 accelerated in the U.S. and COVID-19 case counts increased rapidly. Without any known drugs to treat SARS-CoV-2 and very limited, mostly poor-quality data from Wuhan, initial guidance from the WHO, Society of Critical Care Medicine, the Infectious Diseases Society of America and the National Institutes of Health recommended use of evidence-based supportive care and recommended against the use of investigational therapies outside of a clinical trial.

Based on the results of a convenience sample of Vizient members surveyed in mid-March, at the start of community spread of SARS-CoV-2 in the U.S., use of therapies outside of a clinical trial for the treatment of COVID-19-associated pneumonia was common. The trend to use unproven therapies during the COVID-19 pandemic has caused several practitioners to publicly opine that even in the face of extraordinary pressure to do something, practitioners should continue to be committed to an evidence-based approach to clinical decision-making.<sup>2-4</sup> The physicians argue that the lessons learned from past infectious disease outbreaks have taught the medical community that bypassing evidence-based principles can do more harm than good, including:

- **Disincentivizing participation in clinical trials** by administering drugs off-label, through compassionate use programs and in uncontrolled trials. During the Ebola outbreak of 2014, numerous agents were tested against the virus, but none were definitively proven to be safe or efficacious because of the lack of controlled studies.<sup>5</sup>
- **Causing patient harm** by not making therapeutic decisions with clinical equipoise. For example, results of a systematic review of the treatment effects of ribavirin during the SARS-CoV outbreak of 2003 suggest that it may have caused more harm than benefit to infected patients.<sup>2</sup>

While lessons from past outbreaks are important, the COVID-19 pandemic is unique in several aspects, including the rapidity at which clinical trials have been initiated by national and international organizations, the volume and the speed of dissemination of investigator-initiated research, the retracting of a major study and the outsized role of the media. As one practitioner eloquently stated about the influence of media during this pandemic, “Suddenly for the first time, we do what we have always done — provide evidence-based supportive care for those who need it — and the bright light of the media [social and mainstream] is upon us questioning every move.”<sup>6</sup>

Once the pandemic subsides, only a systematic review of data will reveal what harms, if any, were caused by relaxing evidence-based practice during the COVID-19 pandemic, and if treating patients with evidence-based supportive care alone yielded better outcomes.<sup>7</sup> Vizient plans to conduct a national survey of its members to determine what structures and processes were implemented during the COVID-19 pandemic to try to balance the use of evidence-based supportive care with the use of unproven therapies. Results will be presented in the next iteration of the Drug Price Forecast, scheduled for release in January 2021.

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# Crafting a financial response to COVID-19: The role of biosimilars

With the overwhelming focus on the clinical and economic impact of the COVID-19 crisis, it would be easy to overlook one of the most critical strategies to lower drug expense: the continued adoption of biosimilars. While the rate of uptake remains slow, the market continues to diversify with more competitive versions of prominent biologics being marketed. In addition, on March 23, 2020, many biologics that were previously regulated as drugs, such as insulins, were officially designated as biologics and can now be considered for biosimilar development.<sup>1</sup> As a result, health care organizations should continue to promote biosimilar evaluation and use as part of their efforts to offset the economic consequences of COVID-19.

When reviewing the current market share of biosimilars compared to originator products, we see substantial variations across molecules (Table 14). For filgrastim — the product for which biosimilars and related biologics have been in the market the longest — the competing molecules dominate purchases compared to the originator. In contrast, biosimilars of infliximab lag far behind the originator. For some biologics such as pegfilgrastim, the originator’s differentiated delivery mechanism now leads the market. In the short term, more suppliers are anticipated to enter the market with additional copies of the same molecules (Table 15).

**Table 14. National biosimilar market share (in dollars), April 2020**

Originator	Originator market share, %	Biosimilar	Biosimilar market share, %	Modified formulation	Modified formulation market share, %
Filgrastim	38	Filgrastim-sndz	42	N/A	N/A
		Filgrastim-aafi	7		
		Tbo-filgrastim <sup>a</sup>	14		
Infliximab	89	Infliximab-dyyb	8	N/A	N/A
		Infliximab-abda	3		
Pegfilgrastim	17	Pegfilgrastim-jmdb	5	Pegfilgrastim on-body injector	60
		Pegfilgrastim-cbqv	17		
		Pegfilgrastim-bmez	1		
Rituximab	82	Rituximab-abbs	11	Rituximab subcutaneous	6
		Rituximab-pvvr	1		
Trastuzumab	70	Trastuzumab-anns	26	Trastuzumab subcutaneous	1.3
		Trastuzumab-dkst	1		
		Trastuzumab-qyyp	< 1		
		Trastuzumab-pkrb	< 1		
Bevacizumab	71	Bevacizumab-awwb	28	N/A	N/A
		Bevacizumab-bvzr	1		

Data derived from IQVIA SMART database.<sup>2</sup>

<sup>a</sup> tbo-filgrastim, while not technically a biosimilar, is frequently treated as such in practice.

**Table 15. Short-term biosimilar pipeline: Products with pending user fee goal dates**

Pending biosimilar	Supplier	Estimated user fee date
Bevacizumab (SB8)	Samsung Bioepis and Merck	Sep 2020
Rituximab (ABP 798)	Amgen and Allergan	Dec 19, 2020
Bevacizumab (MYL-14020)	Mylan and Biocon	Dec 27, 2020
Pegfilgrastim (MSB11455)	Fresenius Kabi	Mar 27, 2021

Data derived from Informa website.<sup>3</sup>

## Current and future biosimilar development

All eyes remain squarely focused on 2023, when competition to adalimumab is finally expected to enter the market.<sup>4</sup> Due to a patent litigation settlement, Abbvie has secured additional time until competing products enter the market. At present, there are five versions of the biosimilar adalimumab that have already been approved and an estimated six additional products are in phase 3 development.<sup>5,6</sup> As total U.S sales of adalimumab reach \$22 billion,<sup>7</sup> it is understandable that more competitors continue to eye entry in this space.

Beyond adalimumab, bringing insulins under regulation as biologics creates the opportunity for the approval of interchangeable versions of these commonly used products. Aspart and insulin glargine — two analog versions of insulin — are in phase 3 development, but no applications have been officially filed.<sup>6</sup>

The development pathway for other monoclonal antibodies is beginning to mature. Biosimilar versions of both eculizumab and natalizumab have reached phase 3 status.<sup>6</sup> However, it was recently announced that Alexion, the supplier of originator eculizumab, reached a patent litigation settlement with Amgen, which is currently developing a biosimilar, to prevent this competition from reaching the market until March 1, 2025.<sup>8</sup>

## Have we solved the reimbursement challenge yet?

Ensuring complete and adequate reimbursement remains an issue. In a recent analysis published in the *Journal of the American Medical Association*, the specialty drug coverage decisions of the 17 largest U.S. commercial health plans were reviewed to assess the characterization of the nine biosimilars available at that time.<sup>9</sup> Only seven of 17 plans designated biosimilars as preferred in at least one decision, and only two of the plans identified biosimilars as preferred in 50% or more of decisions.<sup>9</sup> Members must continue to work with their colleagues that manage payer relationships to promote biosimilars. Supporting greater payer recognition for biosimilars remains an essential element of our ongoing advocacy strategy.

## Next steps

While COVID-19 may have redirected some of the focus previously directed at biosimilar consideration, it has not eroded all momentum. The steady introduction of additional competition within existing categories and the ongoing development of biosimilars for other molecules should inspire confidence in this market. Biosimilars should not be viewed as an alternative endeavor separate from COVID-19 recovery, but rather as an integral component of improvement plans. In addition to clinical and operational adoption, members must partner with their billing and finance offices to address the reimbursement challenges that have limited uptake. Finally, Vizient encourages members to partner with us on **advocacy opportunities** to articulate the critical need for biosimilars and other initiatives that drive and sustain competition.

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## In summary: Where do we go from here?

In spite of its tremendous impact, COVID-19 didn't so much create new challenges for health care as it magnified the multitude of fractures and fissures that already existed. For example, drug shortages predated COVID-19, but the pandemic has elevated the awareness of the fragility of the supply chain during any sort of disruption. Verifying clinical trial data and translating the findings into interventions that drive meaningful outcomes have long been a source of concern, particularly for novel, high-cost pharmaceuticals. However, COVID-19 has focused attention on the perils of accelerated publication and the difficulty of altering clinical practice within a short period of time. Finally, the biggest issue has been our current health care economic model's limitations, where an event like COVID-19 creates both financial and clinical hardship by impairing the ability to deliver routine care (e.g., elective surgeries and vaccinations). The resulting financial responses (e.g., furloughs and hospital closures) make any efforts toward helping vulnerable populations that much more challenging.

Given the sizeable amount of financial and resource investment in COVID-19 research, it seems reasonable to anticipate more options will become available to manage this illness, including the introduction of vaccines. Therefore, at some point we will be able to resume a less "socially distant" experience in both clinical practice and daily life. We cannot under any circumstances resume an equally distant approach to the way in which we deliver health care or confront inherent weaknesses in our practice settings. Increasing the resiliency of the supply chain, defining the clinical value of all drugs new or old, ensuring our practice standards reflect the best data available to clinicians and implementing a methodology that balances economic impact with the quality of patient outcomes must be part of an integrated, coordinated strategy. The economic, professional and personal toll has been too great for us to miss this opportunity for meaningful improvement that benefits all of the communities we serve.

Vizient remains committed to helping each of our members maximize this opportunity. We applaud the courage you have demonstrated during this most trying of times and will support you in achieving the goal of more resilient, accessible and equitable care.





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