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.

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.

- 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 October 1, 2018, through September 30, 2019. 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 Food and 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.

- 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.
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Executive overview

Executive summary

What do the numbers tell us?

Overall, the projection indicates a continuation of the sustained modest growth we have seen over the last few years rather than the double-digit percentage increases seen at the start of the specialty pharmacy expansion. Nevertheless, prices for some individual medications are expected to grow at a much faster rate.

Furthermore, even very modest growth can translate into significant price increases. The Vizient membership currently accounts for approximately $70 billion in total drug spend; based on that total, our projected 3.59% overall increase would translate to over $2.5 billion in additional spend.

It is helpful to remember that other factors such as volume changes and new product introductions must be considered when preparing a drug budget. The August 1, 2019, edition of the *American Journal of Health-System Pharmacy* reports that volume and mix increased by 2.4% in nonfederal hospitals in calendar year 2018 and by 8.4% in clinics (including both physician offices and outpatient clinics). In addition, the introduction of new products accounted for 2.8% of expenditure growth for nonfederal hospitals and 5.8% of growth for clinics during the same time frame. Both sets of statistics reveal the increasing influence of the expansion of non-acute care on health-system practice and expense.

As a result, while pricing increases are projected to remain moderate, overall current drug expense means that any additional pricing change will have substantial financial consequences for pharmacy providers. Additional insight can be gleaned by looking at the drugs responsible for the greatest portion of overall spend.

Table 1. Summary of projected drug price inflation, July 1, 2020-June 30, 2021

<table>
<thead>
<tr>
<th>Product group</th>
<th>Vizient predicted price change, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contract products</td>
<td>3.02</td>
</tr>
<tr>
<td>Noncontract products</td>
<td>3.88</td>
</tr>
<tr>
<td>Total weighted average</td>
<td>3.59</td>
</tr>
<tr>
<td>drug price inflation estimate</td>
<td></td>
</tr>
</tbody>
</table>

Estimates based on Vizient member data for October 1, 2018-September 30, 2019. All classes of trade; excludes 340B purchases.
Top 20 drugs by spend and projected increase

Table 2 ranks the 20 drugs with the highest total spend for Vizient members. Table 3 shows the drugs with the largest projected increases in member spend due to price growth.

There are several things we can discern from these tables. First, the impact and influence of biologic drugs — including recombinant pharmaceuticals, naturally derived products, and vaccines — cannot be overstated. Of the top 20 medications by spend, only one product, etelcalcetide, does not fit the definition of a biologic agent. Similarly, the influence of oncology and oncology-related drugs,

### Table 2. Top 20 drugs by total spend among Vizient members

<table>
<thead>
<tr>
<th>Rank</th>
<th>Drug (brand name)</th>
<th>Rank</th>
<th>Drug (brand name)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Adalimumab (Humira)</td>
<td>11</td>
<td>Immune globulin, proline (Privigen, Hizentra)</td>
</tr>
<tr>
<td>2</td>
<td>Rituximab (Rituxan)*</td>
<td>12</td>
<td>Bevacizumab (Avastin)*</td>
</tr>
<tr>
<td>3</td>
<td>Infliximab (Remicade)*</td>
<td>13</td>
<td>Ocrelizumab (Ocrevus)</td>
</tr>
<tr>
<td>4</td>
<td>Pembrolizumab (Keytruda)</td>
<td>14</td>
<td>Trastuzumab (Herceptin)*</td>
</tr>
<tr>
<td>5</td>
<td>Etanercept (Enbrel)</td>
<td>15</td>
<td>Eculizumab (Soliris)</td>
</tr>
<tr>
<td>6</td>
<td>Ustekinumab (Stelara)</td>
<td>16</td>
<td>Etelcalcetide (Parsabiv)</td>
</tr>
<tr>
<td>7</td>
<td>Nivolumab (Opdivo)</td>
<td>17</td>
<td>Pneumococcal 13-valent conjugate vaccine (Prevnar 13)</td>
</tr>
<tr>
<td>8</td>
<td>Pegfilgrastim (Neulasta)*</td>
<td>18</td>
<td>Vedolizumab (Entyvio)</td>
</tr>
<tr>
<td>9</td>
<td>Alteplase (Activase, Cathflo)</td>
<td>19</td>
<td>Immune globulin, glycine (Gamunex-C, Gammaked)</td>
</tr>
<tr>
<td>10</td>
<td>Denosumab (Prolia, Xgeva)</td>
<td>20</td>
<td>Secukinumab (Cosentyx)</td>
</tr>
</tbody>
</table>

*Based on Vizient member data for October 1, 2018-September 30, 2019.
*Biosimilar competitor currently approved and marketed.

### Table 3. Top 20 drugs by size of projected price increase

<table>
<thead>
<tr>
<th>Rank</th>
<th>Drug (brand name)</th>
<th>Rank</th>
<th>Drug (brand name)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Adalimumab (Humira)</td>
<td>11</td>
<td>Nivolumab (Opdivo)</td>
</tr>
<tr>
<td>2</td>
<td>Ustekinumab (Stelara)</td>
<td>12</td>
<td>Indomethacin (generic)</td>
</tr>
<tr>
<td>3</td>
<td>Etanercept (Enbrel)</td>
<td>13</td>
<td>Golimumab (Simponi)</td>
</tr>
<tr>
<td>4</td>
<td>Pembrolizumab (Keytruda)</td>
<td>14</td>
<td>Daratumumab (Darzalex)</td>
</tr>
<tr>
<td>5</td>
<td>Secukinumab (Cosentyx)</td>
<td>15</td>
<td>Abatacept/maltose (Orencia)</td>
</tr>
<tr>
<td>6</td>
<td>Alteplase (Activase, Cathflo)</td>
<td>16</td>
<td>Denosumab (Prolia, Xgeva)</td>
</tr>
<tr>
<td>7</td>
<td>Vasopressin (Vasostrict)</td>
<td>17</td>
<td>Acetaminophen (Ofrimev)</td>
</tr>
<tr>
<td>8</td>
<td>Tofacitinib (Xeljanz)</td>
<td>18</td>
<td>Immune globulin, proline (Privigen, Hizentra)</td>
</tr>
<tr>
<td>9</td>
<td>Certolizumab pegol (Cimzia)</td>
<td>19</td>
<td>Immune globulin, glycine (Gamunex-C, Gammaked)</td>
</tr>
<tr>
<td>10</td>
<td>Vedolizumab (Entyvio)</td>
<td>20</td>
<td>Bevacizumab (Avastin)*</td>
</tr>
</tbody>
</table>

*Based on Vizient member data for October 1, 2018-September 30, 2019.
*Biosimilar competitor currently approved and marketed.
disease-modifying antirheumatic drugs (DMARDs), and immunomodulators on overall spend remains consistent and substantial. Of the 20 drugs listed in Table 2, 14 fall into one of those categories.

While these findings will come as no surprise to readers of previous editions of the Drug Price Forecast, these top-spend lists emphasize the ongoing need for evaluation and adoption of biosimilars. As of the end of 2019, a total of 26 biosimilars have been approved in the United States, and 11 have entered the market. Their impact on costs continues to grow. In our July 2019 forecast, infliximab and pegfilgrastim were ranked as the 2nd and 5th most commonly purchased drugs by overall spend, respectively. In this edition of the forecast, they are now 3rd and 8th. While that degree of expense erosion seems modest, it actually reveals a significant, demonstrable, and long-anticipated impact on the market overall. That migration must continue, especially for the newer agents occupying top spend categories.

Whereas agents such as infliximab, pegfilgrastim, and trastuzumab used to occupy the top of lists such as those in Tables 2 and 3, those positions are now taken by the next generation of agents in these categories. Within the DMARD category, drugs such as ustekinumab, secukinumab, and vedolizumab now have a greater influence on expenditure. Immunotherapy products like pembrolizumab and nivolumab dominate the oncology markets. Failure to embrace biosimilars in the near term will create even more financial peril in the future as newer biologics occupy the positions once held by the drugs that are now facing competition for the first time.

**Good and bad news for other drugs with large projected price increases**

Although biologic drugs dominate many aspects of spend, we expect that certain small-molecule medications will have a substantial impact on costs. Two of these are intravenous (IV) acetaminophen and vasopressin. There is good news for the former and potentially bad news for the latter.

For IV acetaminophen, market exclusivity and patent protection are expected to expire in December 2020, and there will likely be numerous abbreviated new drug applications (ANDAs) and 505(b)(2) versions of this product entering the market. This level of competition should bring meaningful pricing relief in 2021. However, the same cannot be said for vasopressin. While market exclusivity has expired for this agent, numerous patents could protect it from competition until 2035. Patent challenges are under way; Vizient will continue to monitor the potential financial impact of this drug and advocate for legislation that limits how long competition can be delayed.

Finally, the pharmaceutical supply chain continues to see unusual pricing behavior for novel drugs. In this edition of the forecast, for example, the indomethacin suppository formulation has one of the largest anticipated price increases. Vizient continues to support numerous pieces of legislation intended to enable the entry of competitors for medications with few manufacturers when those medications are subject to egregious price increases.

**Challenges and recommendations for success**

A great deal can be learned from review of member purchasing activities. Even more can be determined from direct engagement with our members. Thanks to insights gained through our continuing conversations with members via routine business, network activities, and our multiple advisory and contracting councils, we have identified and validated the top concerns presently confronting our members and can offer strategic insights to help them overcome the barriers they face. These issues and strategies are summarized in Table 4.

The pharmacy landscape continues to be extremely complex — regulatory issues, financial pressures, clinical requirements, and forecast expectations must all be anticipated and managed. However, organizations that can successfully navigate these challenges will not just succeed but thrive. Our goal, as always, is to help our members do just that.

**Table 4. Pharmacy challenges and strategies**

<table>
<thead>
<tr>
<th>Challenges</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Drug shortages</strong></td>
<td>As documented in our 2019 drug shortages survey, the labor cost incurred for management of drug shortages is an estimated $359 million annually. Several legislative, regulatory, and third-party initiatives to provide long-term solutions are under way.</td>
</tr>
<tr>
<td><strong>Biosimilars (and payer influence)</strong></td>
<td>Meaningful uptake of biosimilars is finally occurring, leading to an overall reduction in expenditures for originator biologics. The number of approved and marketed biosimilars continues to increase. However, the biggest hurdle to an even stronger embrace of biosimilars is payers’ formulary decisions and their impact on reimbursement. Variations in coverage require providers to stock multiple versions of the same product (originator and biosimilar), which is definitely not the intention of biosimilars.</td>
</tr>
</tbody>
</table>
Challenges

Cost of new drugs, both new molecules and new formulations
In 2019, the first multimillion-dollar treatment was approved. This year could bring several more novel but extremely expensive gene therapies. In addition, new formulations of older pharmaceuticals (e.g., premixed insulin) rather than new molecules have resulted in higher costs in some cases. As a result, members must now assess the cost of rarely used, extraordinarily expensive drugs as well as frequently used agents with modest cost increases.

USP enforcement
One of the most prominent dates on members’ calendars has been December 1, 2019 — the original deadline for full compliance with the revised USP standards. As discussed in the Acute Care section, that date has been delayed by an appeal of the standards, resetting the enforcement date to either mid-2020 or even December 2021. Uncertainty about enforcement by various regulatory and accreditation agencies has made it more difficult for members to determine the time frame for complete adherence and plan for implementation.

Potential legislative action
Drug prices are a prominent issue for the US population as a whole, especially in view of the coming presidential election cycle. A recent survey of potential voters found that high drug prices were the health care-related topic of greatest concern for Democrats, Republicans, and independents alike. As a result, and despite the unlikelihood of bipartisan action in other spheres, there is potential for legislative or executive actions to occur both before and after the 2020 elections.

Vizient strategies

Maximizing the value of the Novaplus® program and the Vizient resources available to assist with the management of drug shortages
Through our Novaplus portfolio, Vizient has been able to minimize the impact on our members of many of the shortages that presently plague the market. The Novaplus Enhanced Supply strategy will ensure additional production of essential medications — propofol, magnesium sulfate, protamine, thiamine, phenylephrine, oxycotin, meropenem, enoxaparin, levothyroxine, glucagon, and octreotide — to help prevent supply interruptions. While shortages will still occur, we have enlisted our internal expertise as well as insights from our members to develop strategies to manage some of the most clinically problematic shortages. And our Pharmacy Program and public policy office are both committed to advocating for legislative changes that can provide sustainable solutions and a high-quality supply chain for critical drugs.

Continued support for the biosimilars market
While uptake of biosimilars has gradually improved, the oncology market will be the true test of whether a model that is both clinically accepted and financially viable can be sustained. Vizient offers educational, clinical, and analytical resources to help our members evaluate the opportunities presented by biosimilars, such as side-by-side comparisons for drugs such as rituximab, trastuzumab, and bevacizumab, and a comprehensive value analysis tool. We are also working with members to identify strategies for addressing the reimbursement hurdles that have limited biosimilar use or required members to keep multiple versions of the same biologic in inventory.

Focus on advocacy
Successfully addressing the many issues confronting pharmacy requires advocacy. The Vizient pharmacy team and our public policy office are working to maximize every legislative opportunity to advance our members’ cause and remove the barriers to cost-effective care. Our June 2019 Congressional briefing demonstrated both our commitment to amplifying our members’ voices and the impact of our platform to drive sustainable change.

Strategic focus on pharmacy
At Vizient, we have consistently held that pharmacy must be treated as an essential element of any organization’s strategic plan, given its impact on the cost and quality of patient care across practice environments. Pharmacy is an integral component of efforts to reduce inpatient length of stay, expand medication management to include retail or specialty pharmacy, promote population health, and decrease opioid abuse. The involvement of pharmacy in payer negotiations is another area in which pharmacy leadership is critical to success.

Partnering with Vizient
The Vizient Integrated Pharmacy Solution continues to grow in scope and depth of services to provide sourcing opportunities, advanced analytics, consulting support, clinical resources, educational materials, thought leadership, and advocacy — all geared toward addressing the array of issues that challenge pharmacy providers. Whether a health care organization needs help with drug shortage management, evaluating and adopting biosimilars to lower drug spend, or preparing to meet new standards for sterile and hazardous drug compounding, Vizient has the resources and expertise our members need. Together, we can anticipate the changes that influence drug spend and find ways to mitigate challenges.
A closer look by segment

Acute care

Recent regulatory, reimbursement, and drug shortage policy changes have had a heavy impact on the acute care market. Additional upcoming regulatory issues that will affect acute care facilities include antimicrobial stewardship policies, the Drug Supply Chain Security Act, compounding standards established by the US Pharmacopeia (USP), and new requirements for pharmacy technicians.

Antimicrobial stewardship

The Centers for Medicare & Medicaid Services’ Conditions of Participation require all acute care hospitals that participate in Medicare or Medicaid to develop and implement an antibiotic stewardship program as part of their infection control programs. Stewardship programs must be implemented by March 30, 2020.

In addition, The Joint Commission has expanded its antimicrobial stewardship program standards for acute care hospitals, critical access hospitals, and nursing homes (MM.09.01.03) to include accredited ambulatory care centers. This expansion took effect January 1, 2020.

Drug Supply Chain Security Act

Effective November 27, 2020, dispensers will only be allowed to accept serialized drug products encoded with product identifiers, as both 2D barcode standardized numerical identifiers and human-readable text. Dispensers will also be required to use these identifiers to verify any suspect products at the package level — i.e., the smallest individual saleable unit of product for distribution by the manufacturer or repackager that is intended for ultimate sale to the dispenser.

USP compounding standards

On September 23, 2019, USP announced that enforcement of the compounding standards laid out in general chapters <795>, <797>, and <825> (covering nonsterile and sterile preparations and radiopharmaceuticals, respectively) is being delayed. The extension is the result of multiple appeals about beyond-use dating, alternative technologies and techniques, and applicability of the standards to veterinary practitioners. If the appeals are denied, the USP chapters may become enforceable on June 1, 2020. If the appeal is remanded, enforcement may be delayed until at least December 1, 2021, because of the need to update the chapters and open the changes for public comment. In the interim, the current chapters <795> (last revised in 2014) and <797> (last revised in 2008), including the section “Radiopharmaceuticals as Compound Sterile Products,” will remain in force.

However, USP general chapter <800> (“Hazardous Drugs — Handling in Health Care Settings”) is not subject to any pending appeals and therefore became official on December 1, 2019. USP noted in its September letter that while the other chapters are postponed, USP chapter <800> is “informational and not compendially applicable.” USP encourages utilization of the chapter <800> standards in the interest of advancing public health.

USP plays no role in enforcement, but states and other regulators may make their own determinations regarding the enforceability of chapter <800>. Many state boards of pharmacy voted to delay its enforcement until after December 1, 2019, to allow time for the rulemaking process.

Conforming to the revised USP chapters <795> and <797> and the new chapters <800> and <825> will require much preparation and careful budget considerations. Some of the changes that will be necessary to ensure compliance and patient safety will increase overall pharmacy spending and may require upfront funding. Areas for budget consideration include facility design, quality assurance, and personnel training.

Pharmacy technicians

Eligibility to take the pharmacy technician certification exam has previously required only a high school diploma. As of January 1, 2020, however, that standard has been replaced. Under the new requirements, applicants will need to complete an education training program or have equivalent work experience to be eligible for certification.

Vizient offers support to our members through education, solutions, and services to help them prepare for upcoming regulatory deadlines.

Contact us at pharmacyquestions@vizientinc.com for more information.
Specialty pharmaceuticals

One recent innovation in the Drug Price Forecast was the analysis of specialty drug price inflation rates for biologic and nonbiologic products. Our current projections are shown in Table 5, subdivided into biologic and nonbiologic categories based on the type of approval the drug received from the Food and Drug Administration (FDA).

Table 5. Estimated specialty drug price inflation rates, July 1, 2020-June 30, 2021

<table>
<thead>
<tr>
<th>Category</th>
<th>Vizient predicted price change, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biologics</td>
<td>3.56</td>
</tr>
<tr>
<td>Nonbiologics</td>
<td>3.13</td>
</tr>
<tr>
<td><strong>Total weighted average drug price inflation estimate</strong></td>
<td><strong>3.36</strong></td>
</tr>
</tbody>
</table>

Estimates based on Vizient member data for October 1, 2018-September 30, 2019.

The breakout of specialty drug price inflation rates resulted in an average 3.36% predicted price inflation. Perhaps unsurprisingly, prices of biologic medications are expected to increase more quickly than those of nonbiologics. The overall specialty drug inflation rate is similar to the general drug inflation rate of 3.59% we have predicted for this time period. However, since the prices of specialty drugs tend to be higher than those of nonspecialty medications, this inflation rate suggests that organizations will likely need to increase their drug budgets.

Impact of specialty pharmaceuticals

Specialty pharmaceuticals have continued to dominate all aspects of drug approvals and purchasing and have a disproportionate impact on pharmaceutical costs. Although they only account for 2.2% of total prescription volume, specialty drugs now account for 49.5% of total spending by institutional and retail pharmacy settings. About half of the more than 40 novel molecular entities approved in 2019 can be classified as specialty drugs. To cope with the increase in specialty medications, health systems have worked to expand their expertise and capabilities to support specialty pharmacy services, to avoid losing the capacity to manage their patients holistically.

Summary

The dynamics of the specialty pharmacy landscape and the structure of the investigational drug pipeline reflect the continued importance of this class of pharmaceuticals and the absolute necessity of a defined specialty pharmacy strategy for health systems. At Vizient, we continue to enhance our offerings to address every aspect of this market and provide solutions to the challenges facing our members. We know that our members must measure their successes in terms of cost, quality, and market performance, and that this is especially true in the context of specialty pharmacy practice.
Non-acute and alternate-site care

Given the widespread concern about rising health care costs, the need to deliver high-quality, cost-effective care outside of an inpatient hospital setting continues to be an area of focus. As Figures 1 and 2 show, the focus on non-acute drug spend can be understood both relative to overall drug spend and with regard to the year-over-year change in spend in the various non-acute markets. The increase in pharmacy expense in settings such as clinics (including physician offices and outpatient clinics) and home health care providers is even greater than the growth of drug spend in the traditional health system setting.

Figure 1. Expenditures as a percentage of total drug spend, by sector

![Pie chart showing drug expenditure percentages by sector]

Data derived from Schumock et al.¹
Abbreviation: HMO = health maintenance organization.

Figure 2. Total drug expenditures for 2018 by sector and change from 2017

![Bar chart showing drug expenditures and change from 2017 by sector]

Data derived from Schumock et al.¹
Abbreviation: HMO = health maintenance organization.

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The alternate-site pharmacy practice setting is essential to providing integrated and coordinated care that meets the highest clinical, financial, and regulatory standards, so it is important to know which products have greatest impact in this critical market. Table 6 shows the highest-spend non-acute drugs among Vizient members.

### Table 6. Top 10 drugs based on non-acute member spend among Vizient members

<table>
<thead>
<tr>
<th>Rank</th>
<th>Drug (brand name)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Adalimumab (Humira)</td>
</tr>
<tr>
<td>2</td>
<td>Etanercept (Enbrel)</td>
</tr>
<tr>
<td>3</td>
<td>Ustekinumab (Stelara)</td>
</tr>
<tr>
<td>4</td>
<td>Infliximab (Remicade)</td>
</tr>
<tr>
<td>5</td>
<td>Etelcalcetide HCl</td>
</tr>
<tr>
<td>6</td>
<td>Denosumab (Prolia, Xgeva)</td>
</tr>
<tr>
<td>7</td>
<td>Secukinumab (Cosentyx)</td>
</tr>
<tr>
<td>8</td>
<td>Rituximab (Rituxan)</td>
</tr>
<tr>
<td>9</td>
<td>Tofacitinib citrate (Xeljanz)</td>
</tr>
<tr>
<td>10</td>
<td>Somatropin (multiple brands)</td>
</tr>
</tbody>
</table>

Based on Vizient member data for October 1, 2018-September 30, 2019.

There are several things to note about this list. First, 8 of these products also appear in the top 20 for overall spend among Vizient members, which were listed in Table 2. Similarly, therapeutic categories such as the biologic DMARDs, oncology products, and drugs used for the treatment of multiple sclerosis figure prominently in the non-acute setting. As a result, many of the recommendations for health systems, such as promoting use of biosimilars and managing reimbursement, apply in the non-acute setting as well.

- Advancing biosimilars: Given the expansive use of biologics, it is essential for non-acute providers, like their health system counterparts, to continue to encourage the adoption of biosimilars. Providers that fail to fully exploit this market will be more susceptible to the pressure of ever-higher drug costs.
- Managing reimbursement as well as cost: One of the challenges in the biosimilars market is the lack of alignment in formulary coverage status among payers — a challenge that applies to non-acute providers as well as health systems. Therefore, providers must continue to focus on ensuring appropriate reimbursement and engaging with payers to address coverage issues.

In addition, non-acute providers must remain vigilant about new market disruptors. Rising drug costs will continue to create an environment that will attract efforts at disintermediation — whether those take the form of reimbursement changes from the government or private payers, consolidation across the health care landscape, or increasingly influential third parties such as Amazon. Non-acute practitioners must find ways to establish their influence in novel areas. One such opportunity is in the retail pharmacy space.

### Summary

The movement of patient care away from the traditional inpatient setting will continue to create greater demand for non-acute services that provide high-quality care. As a result, pharmacy providers must be knowledgeable about the practice, regulatory, and financial issues that have the greatest impact on this market. Vizient and our colleagues at Provista®, our supply chain partner serving the non-acute market, will continue to expand our offerings to anticipate these challenges and improve our members’ ability to foresee and adapt to market changes.
As in other areas, pediatric pharmaceutical costs are rising as a result of the targeting of rare diseases that require specialty or orphan drugs.

Approximately 80% of known rare diseases are based on genetic mutations. Five of the 10 commercially available gene therapy products are used to treat pediatric patients. Gene therapy has been leading the high-cost drug list in pediatrics for 2019 and the pipeline is expanding quickly, as biologic companies race to release new drugs. One new gene therapy currently entering phase 3 trials, alicaforsen (Camligo, Atlantic Healthcare), is an antisense oligonucleotide targeting gene messengers involved in inflammation for the treatment of inflammatory bowel disease. Use of gene therapy requires a multidisciplinary team to analyze handling and delivery of the drugs as well as the financial impact on the overall hospital budget.

The recent introduction of onasemnogene abeparvovec-xioi (Zolgensma, AveXis) for the treatment of spinal muscular atrophy (SMA) has had a significant impact on pharmacy budgets. Previously, nusinersen (Spinraza, Biogen) was the only treatment option available for these patients. Many states have either already added screening for SMA to routine newborn testing or are in the process of adding it in 2020, a development that will allow providers to identify SMA at a much earlier age and begin treatment before symptoms become severe.

Biosimilars approved in 2019 including bevacizumab (Avastin, Genentech), infliximab (Remicade, Genentech) and rituximab (Rituxan, Genentech) should help reduce overall cost increases. The originator biologic products have ranked among the top 10 drug spend among self-governed children’s hospitals year-over-year, so biosimilar competition in this space is awaited with great anticipation. Costs associated with the treatment of pediatric ulcerative colitis, inflammatory bowel disease and Crohn’s disease have been reduced by the introduction of biosimilars for infliximab, despite the fact that there was much resistance to the initial release and coverage decisions were mostly payer driven. Recent updates to payment structures and wider acceptance of biosimilar products has improved the infliximab biosimilar’s penetration of the market.

Approvals of drugs for the pediatric population have been primarily in 3 categories: specialty drugs, gene therapy, and chimeric antigen receptor T-cell (CAR T) treatments. All of these treatments raise budgetary and revenue capture obstacles. To alleviate the burden they impose, careful evaluation is needed before they are added to hospital formularies. Value-based approaches to this evaluation include consideration of quality-adjusted life years, outcomes-based payments, and indication-based pricing. In 2020, it will be important to evaluate payment structures when implementing high-cost drug programs.
No issue facing health care has remained so persistent and enduring as drug shortages. While the actual number of shortages has waxed and waned, the better part of the last 2 decades has been spent in a continuing struggle to maintain access to essential medications. The level of frustration this has engendered, however, has been matched by the agility and resilience of pharmacists and pharmacy buyers as they have skillfully navigated these conditions to protect patients from negative outcomes. However, 2019 may have been a turning point in identifying and taking meaningful steps to address the fundamental issues that contribute to supply interruptions. The events of 2019 also enabled us to demonstrate again the power of the Novaplus private label to minimize the negative consequences of drug shortages on our members. An enhanced supplier strategy announced in November 2019 will further strengthen the level of security we can provide.

What are the causes of drug shortages?

In 2018, in response to a congressional request, the FDA established an interagency Drug Shortages Task Force to study the problem of shortages, prepare a report on their root causes, and make recommendations for enduring solutions. In October 2019, the task force published its report following analysis of data, published research, and meetings with stakeholders (including Vizient) in the private and public sectors. The report identified 3 root causes of drug shortages:

- Lack of incentives to produce less profitable drugs
- Lack of recognition and reward within the market for manufacturers with mature quality management systems
- Logistical and regulatory challenges that make it difficult for the market to recover after a disruption

The task force also identified 3 potential solutions:

- Create a shared understanding of the impact of drug shortages and the contracting practices that may contribute to them.
- Create a rating system to incentivize drug manufacturers to invest in achieving quality management system maturity.
- Promote sustainable private-sector contracts.

Putting solutions into action

The results of the report were extremely valuable. While the identified causes were not a surprise, their characterization in an official report promotes appreciation of the nature and extent of the challenges. At Vizient, we are already working to address the problems identified by the task force and to pursue many of its recommended solutions.

For example, one challenge noted by the FDA is the lack of comprehensive quantification of the costs of managing drug shortages. This past spring, our drug shortages survey revealed that the estimated labor impact of shortage management is 8.6 million hours annually, leading to $359 million in additional costs. Vizient is continuing to work with its members to further assess the financial and clinical impact of drug shortages.

In addition, we are already implementing solutions in line with FDA recommendations. On November 21, 2019, Vizient launched its Novaplus Enhanced Supply strategy to help mitigate drug shortages, in which we are expanding our partnerships with trusted suppliers to provide additional access to and supply of the medications most essential for patient care. The first manufacturer in this enhanced agreement, Fresenius Kabi, will provide access to propofol.

Key points

- Increased transparency and commitment to supply are critical to developing long-lasting solutions to the drug shortage crisis.
- The Novaplus Enhanced Supply strategy reflects our commitment to finding novel mechanisms to help members manage their most critical issues.
- Vizient will continue to advocate for the legislative changes needed to support a high-quality, reliable, and secure supply chain for pharmaceuticals.
magnesium sulfate, protamine, thiamine, phenylephrine, oxytocin, meropenem, enoxaparin, levothyroxine, glucagon, and octreotide. The Novaplus Enhanced Supply strategy focuses on 3 key pillars to support a more robust and stable supply chain:

• Transparency: manufacturing insights to promote stronger supply chain resiliency
• Accountability: strengthened requirements to provide health systems with more seamless continuity of care
• Commitment to supply: increased inventory in the market

All of these components were central to the FDA’s report and are reflected in the strength of our contracting strategies and the Novaplus program to limit the impact of drug shortages. We anticipate that this partnership and the many others expected to follow will help build greater resiliency into the market for critically important pharmaceuticals. Still, we know that even these efforts are not guaranteed to eradicate shortages and we must continue to assist our members when interruptions occur.

Education and advocacy

In addition to our sourcing approach, we at Vizient continue to provide our members with critical information and clinical insights to help them respond to shortages. We strive to provide the most up-to-date information on shortages, including therapeutic alternatives and drug mitigation strategies.

In addition to working directly with the FDA’s Drug Shortage Task Force, our public policy office continues to support legislative initiatives to address supply interruptions. We also engage other agencies about potential governmental actions to increase the supply of essential medications — for instance, by offering insights on the Drug Enforcement Agency’s efforts to address the opioid crisis by limiting access to the active ingredients.

While drug shortages will not end in the near future, we can hope that we have turned a corner and that an increased level of transparency and a commitment to quality manufacturing will reduce the hardship endured by health care organizations, providers, and especially patients.

Novaplus Enhanced Supply strategy

The Vizient private-label brand, Novaplus, is the focus of our strategy to provide greater reliability of supply for essential medications through expanded partnerships with our suppliers.

The strategy is based on 3 pillars that uphold all of our efforts to address the problem of drug shortages:

• Transparency
• Accountability
• Commitment to supply

$359M
Annual cost of labor needed to manage drug shortages

8.6M
Additional labor hours per year

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Biosimilars at the close of their first decade

A refrain from previous versions of the Drug Price Forecast still holds true: Successful development of a robust biosimilar market is critical to any long-term efforts to control global pharmaceutical expenditures in general and the cost of biologics specifically. Although we are nearing the end of the first decade of biosimilars, the size of the market in terms of products available is only now beginning to mature, with more than 2 dozen biosimilars approved by the FDA as of the end of 2019 (Table 7). The market dynamics have substantially changed with the introduction of competition for the 3 Genentech monoclonal antibodies for cancer treatment — rituximab, bevacizumab, and trastuzumab. These agents collectively account for over $14 billion in annual US sales.

The lack of approved and marketed products is therefore no longer a roadblock to biosimilar uptake. As a result, 2020 will truly be a seminal year for the adoption of biosimilars. If there is meaningful uptake of the oncology biosimilars, we may finally begin to see effective competition. Therefore, we must continue to focus on achieving and sustaining that desired level of adoption.

Key points
• 2020 will be a seminal year for biosimilar adoption given the substantial growth of both approved products and those already on the market.
• Vizient continues to provide tools, resources, and support covering all aspects of biosimilar evaluation and adoption to our members.
• Failure to maximize the potential of biosimilars will pose a substantial risk to patient access to critical biologic therapies.

Table 7. FDA-approved biosimilars as of December 2019

<table>
<thead>
<tr>
<th>Drug (brand name)</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Filgrastim-sndz (Zarxio)*</td>
<td>Sandoz</td>
</tr>
<tr>
<td>2. Infliximab-dyyb (Inflectra)*</td>
<td>Celltrion/Pfizer</td>
</tr>
<tr>
<td>3. Etanercept-szzs (Erelzi)</td>
<td>Sandoz</td>
</tr>
<tr>
<td>4. Adalimumab-atto (Amjevita)</td>
<td>Amgen</td>
</tr>
<tr>
<td>5. Infliximab-abama (Renflexis)*</td>
<td>Samsung/ Merck</td>
</tr>
<tr>
<td>6. Adalimumab-abdm (Cyltezo)</td>
<td>Boehringer Ingelheim</td>
</tr>
<tr>
<td>7. Bevacizumab-awwb (Mvasi)*</td>
<td>Amgen/ Allergan</td>
</tr>
<tr>
<td>8. Trastuzumab-dkst (Ogivri)</td>
<td>Mylan</td>
</tr>
<tr>
<td>9. Infliximab-qbtx (Ixfi)</td>
<td>Pfizer</td>
</tr>
<tr>
<td>10. Epoetin alfa-epbx (Retacrit)*</td>
<td>Pfizer</td>
</tr>
<tr>
<td>11. Pegfilgrastim-jndb (Fulphila)*</td>
<td>Mylan</td>
</tr>
<tr>
<td>12. Filgrastim-aafi (Nivestym)*</td>
<td>Pfizer</td>
</tr>
<tr>
<td>13. Adalimumab-adaz (Hyrimoz)</td>
<td>Sandoz</td>
</tr>
<tr>
<td>14. Pegfilgrastim-cqvb (Udenyca)*</td>
<td>Coherus</td>
</tr>
<tr>
<td>15. Rituximab-abbs (Truximab)</td>
<td>Celltrion/Teva</td>
</tr>
<tr>
<td>16. Trastuzumab-pkrb (Herzuma)</td>
<td>Celltrion</td>
</tr>
<tr>
<td>17. Trastuzumab-dttb (Ontuzant)</td>
<td>Samsung/Merck</td>
</tr>
<tr>
<td>18. Trastuzumab-qyyp (Trazimera)</td>
<td>Pfizer</td>
</tr>
<tr>
<td>19. Etanercept-ykro (Eticovo)</td>
<td>Samsung Bioepis</td>
</tr>
<tr>
<td>20. Trastuzumab-anns (Kanjinti)*</td>
<td>Amgen</td>
</tr>
<tr>
<td>21. Bevacizumab-brzr (Zirabeve)</td>
<td>Pfizer</td>
</tr>
<tr>
<td>22. Rituximab-pvrr (Ruxience)</td>
<td>Pfizer</td>
</tr>
<tr>
<td>23. Adalimumab-bwwd (Hadlima)</td>
<td>Merck/Samsung Bioepis</td>
</tr>
<tr>
<td>24. Pegfilgrastim-bmez (Zientzenzo)</td>
<td>Sandoz</td>
</tr>
<tr>
<td>25. Adalimumab-aftz (Abrilada)</td>
<td>Pfizer</td>
</tr>
<tr>
<td>26. Infliximab-aqxq (Avsola)</td>
<td>Amgen</td>
</tr>
</tbody>
</table>

*a Currently on the market.
Equipping our members for success

At Vizient, we are working to provide support and resources to help members evaluate and adopt biosimilars. We recently launched a biosimilar resources webpage, as well as a comprehensive financial analysis tool that allows our members to model the financial opportunity biosimilars may offer their specific organizations. And support for biosimilar uptake is an area of focus for our national sourcing team, pharmacy aggregation networks, Advisory Solutions pharmacists, and our Center for Pharmacy Practice Excellence.

While the number of biosimilars approved and on the market has grown substantially, barriers to adoption still exist. Based on member feedback, we know that the inconsistency of payer formulary decisions continues to create hurdles, as it requires hospitals to stock multiple versions of the same molecule to ensure reimbursement rather than being able to standardize on one, whether originator or biosimilar.

Successful development of a robust biosimilar market is critical to any long-term efforts to control pharmaceutical expenditures.

Inconsistency of payer formulary decisions creates hurdles to biosimilar adoption, requiring hospitals to stock multiple versions of the same molecule to ensure reimbursement rather than being able to standardize on one, whether originator or biosimilar.
Many oncology agents are expected to be approved in 2020 via the 505(b)(2) FDA approval pathway, which opens the market to products that are not necessarily new molecular entities but may have additional indications, dosage forms, strengths, or combinations. These products would create competition in their respective treatment areas.

Changes in utilization for IV and oral antineoplastic agents are shown in Table 8. Since their introduction to the market in 2014, overall spend on PD-1 and PD-L1 inhibitors has steadily increased. Currently, this class encompasses 6 agents and a total of 50 indications, but these numbers are expected to grow over the next several years. At least 4 additional indications for existing medications are expected to be approved in 2020, and 2 new PD-1 agents may be on the market by 2021.

The number of agents and indications for CAR T therapy are also expected to grow, with 2 additional agents likely to file for FDA approval in 2020, increasing the list of indications to 6. An off-the-shelf (allogeneic) T-cell immunotherapy agent is also expected to arrive in late 2020 or early 2021.

Table 8. Change in utilization and pricing for antineoplastic drugs

<table>
<thead>
<tr>
<th>Drug (brand name)</th>
<th>Manufacturer</th>
<th>Utilization change</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intravenous agents</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Atezolizumab (Tecentriq)</td>
<td>Genentech</td>
<td>↑</td>
</tr>
<tr>
<td>Cetuximab (Erbitux)</td>
<td>Lilly</td>
<td>↓</td>
</tr>
<tr>
<td>Ado-trastuzumab emtansine (Kadcyla)</td>
<td>Genentech</td>
<td>↑</td>
</tr>
<tr>
<td>Panitumumab (Vectibix)</td>
<td>Amgen</td>
<td>↔</td>
</tr>
<tr>
<td>Elotuzumab (Empliciti)</td>
<td>Bristol-Myers Squibb</td>
<td>↑</td>
</tr>
<tr>
<td><strong>Oral agents</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Imatinib (Gleevec)</td>
<td>Novartis</td>
<td>↓</td>
</tr>
<tr>
<td>Lenvatinib (Lenvema)</td>
<td>Eisai</td>
<td>↔</td>
</tr>
<tr>
<td>Pazopanib (Votrient)</td>
<td>Novartis</td>
<td>↓</td>
</tr>
<tr>
<td>Erlotinib (Tarceva)</td>
<td>Genentech</td>
<td>↓</td>
</tr>
<tr>
<td>Sorafenib (Nexavar)</td>
<td>Bayer</td>
<td>↓</td>
</tr>
</tbody>
</table>

Based on Vizient member data for October 1, 2018-September 30, 2019.
Infectious disease

This class will remain mostly stable in 2020 with regard to antibacterials and HIV medications, although clinical trial results for a new oral antibiotic for skin and skin structure infections should be final in the latter half of 2020. Many important HIV medications have been losing exclusivity, resulting in additional generic competition in the market. One new HIV medication is expected in 2020.

Prices for hepatitis C medications are expected to remain stable or decline slightly as a result of the reduction in the population of patients with the disease and the fact that many agents in the category are price competitive.

The number of vaccines is expected to increase in 2020, as 2 vaccines are expected to be approved by the FDA this year: one for prevention of Ebola and another for meningococcal disease. Per-dose prices for flu vaccines are likely to rise.

Disease-modifying antirheumatic drugs

Table 9 shows the drugs that account for the largest portion of spend among Vizient members in the DMARD category.

A new product for the treatment of psoriatic arthritis is expected to be approved by the FDA in the second half of 2020, which will affect the DMARD market. Biosimilar uptake in this therapeutic category is also expected to increase.

Table 9. Disease-modifying antirheumatic drugs with highest spend among Vizient members

<table>
<thead>
<tr>
<th>Rank</th>
<th>Drug (brand name)</th>
<th>Rank</th>
<th>Drug (brand name)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Infliximab (Remicade)</td>
<td>6</td>
<td>Golimumab (Simponi)</td>
</tr>
<tr>
<td>2</td>
<td>Adalimumab (Humira)</td>
<td>7</td>
<td>Certolizumab pegol (Cimzia)</td>
</tr>
<tr>
<td>3</td>
<td>Abatacept/maltose (Orencia)</td>
<td>8</td>
<td>Infliximab-dyyb (Inflectra)</td>
</tr>
<tr>
<td>4</td>
<td>Tocilizumab (Actemra)</td>
<td>9</td>
<td>Infliximab-abda (Renflexis)</td>
</tr>
<tr>
<td>5</td>
<td>Etanercept (Enbrel)</td>
<td>10</td>
<td>Tofacitinib citrate (Xeljanz)</td>
</tr>
</tbody>
</table>

Based on Vizient member data for October 1, 2018-September 30, 2019.

Plasma critical care products: IgIV and albumin

Demand for IgIV has remained strong and manufacturers have struggled to supply U.S. providers over the past year. As a result of the ongoing supply challenges, prices are expected to continue their upward trend through 2020 and 2021.

As manufacturers increase output of IgIV in response to demand, albumin, a related end product, is produced in quantities 4 to 5 times higher than immune globulin, creating an abundant supply that continues to drive down prices.
Radiopharmaceuticals

Annual price increases for low-energy radiopharmaceuticals took effect on January 1, 2020. The industry average annual increase is approximately 4%, but there will be variances from supplier to supplier due to differences in third-party manufacturing agreements.

Prices for high-energy radiopharmaceuticals are also now fixed for 2020 on 18F-fluorodeoxyglucose (FDG). As with low-energy products, variations in price may result from differences in third-party manufacturing agreements.

As noted in the Acute Care section of this forecast, enforcement of new standards covering radiopharmaceuticals established in USP general chapter <825> has been delayed indefinitely pending the result of active appeals. Resolution is anticipated sometime this year, which could have a financial impact in on suppliers in late 2020 or early 2021 and lead to potentially significant price increases in 2021. The new effective date, once determined, will be announced at least 6 months in advance.

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