Specialty Medications

NPS defines a specialty medication as a biologic or traditional drug, which requires additional management for a complex, chronic, or life-threatening condition that typically has two or more of the following attributes:

- Treats a condition, which requires intensive clinical monitoring of the patient.
- Requires special patient training or patient compliance assistance.
- Requires special handling, such as storage or preparation.
- Requires special administration by the patient or the healthcare professional.
- Has a limited distribution network.
- Has a high total cost.

The IMS Institute for Healthcare Informatics reported that spending on specialty pharmaceuticals almost doubled from 2010 to 2015, and spending on this subset of drugs was responsible for 70% of overall drug spending growth during this timeframe.

In 2015, spending on these medications reached $150 billion, a more than 20% increase from 2014.[1] Drug spending is anticipated to continue to increase[1] and specialty drug sales will reach $402 billion — 47% of prescription drug spending — by 2020.[2]

As these specialty medications become more widely available and prescribed, strategies to control spending are of paramount importance.

Defining Specialty Drugs

Specialty medications can be small molecules or complex biologics.[2] In general, these medications treat complicated, potentially life-threatening conditions such as cancer, hepatitis, nervous system or blood disorders, and autoimmune conditions.[1,2] Specialty drugs may also be used to treat more common chronic disease states such as asthma or rheumatoid arthritis.[3]

General characteristics of a specialty drug include: a limited distribution network, close patient monitoring, requirements for special handling, a high cost per unit or treatment course, and/or use only in a unique patient population.[2] For 2017, the Centers for Medicare & Medicaid Services (CMS) defines a specialty medication as a drug which costs more than $670 per month.[4]

National Pharmaceutical Services (NPS) defines a specialty medication on the basis of having two or more specific attributes as described in the box to the left. Despite variations in the definition of a specialty drug, there is a general consensus regarding which medications are in the specialty category.[2]

NPS defines a specialty medication as a biologic or traditional drug, which requires additional management for a complex, chronic, or life-threatening condition that typically has two or more of the following attributes:

- Treats a condition that requires intensive clinical monitoring of the patient.
- Requires special patient training or patient compliance assistance.
- Requires special handling, such as storage or preparation.
- Requires special administration by the patient or the healthcare professional.
- Has a limited distribution network.
- Has a high total cost.

Conditions Managed by Specialty Drugs

Specialty drugs primarily treat complex chronic conditions including autoimmune diseases, cancer, hepatitis C, multiple sclerosis, etc.[2]

Autoimmune Conditions

Autoimmune diseases encompass conditions including rheumatoid arthritis, psoriasis, and inflammatory bowel diseases (Crohn's disease, ulcerative colitis). These diseases occur when the immune system inappropriately attacks healthy cells and tissues. These chronic conditions are frequently treated with complex, powerful medications, such as biologics, to dampen the immune system response.[8,9]

Many of these medications are specialty drugs (e.g., the biologics Humira and Enbrel). Spending on autoimmune diseases is rising and increased to $30 billion (+25%) from 2014 to 2015.[10] Spending on this subset of specialty medications is not likely to slow as new agents are expected to gain FDA approval and currently approved drugs receive expanded indications.

Cancer

Oncology represents one of the fastest growing segments of the specialty market. From 2011 to 2015, annual U.S. spending on this class of medications increased from $24 billion to $39 billion.[10] Spending growth in this category is expected to continue. Approximately half of the specialty products granted FDA-approval in 2015 received a cancer indication.[6,11]

Many of these new agents are being developed to target specific cancer mutations, are approved in conjunction with a companion diagnostic test, and are indicated for use only in the population of patients who exhibit the specific mutation.[12] In addition, more cancer medications are oral capsules or tablets taken continuously until disease progression or side effect intolerance.[13]

Hepatitis C

In the last few years, approval of medications from a new class of hepatitis C drugs — the direct-acting antiviral (DAA) agents — has changed the course of hepatitis C virus (HCV) treatment. These DAA agents allow treatment shorter regimens (~12 weeks), better tolerability (fewer side effects), and higher cure rates (90 to 100%). However, these improvements are more expensive. The cost of a 12-week treatment course with these new agents can range from $66,000 to $180,000, and spending on this subset of specialty drugs demonstrated a corresponding increase from $2.1 billion in 2011 to almost $19 billion in 2015.[10,14]

Multiple Sclerosis

Multiple sclerosis (MS) is an immune-mediated disease affecting the central nervous system (CNS), and can lead to disability.[15] Numerous disease-modifying therapies have been approved by the FDA, and although they decrease the likelihood of experiencing MS symptoms, they cannot cure the condition.[16]

These therapies may be injected or taken orally. Regardless of the route of administration, patients receiving these medications generally require careful monitoring for potentially serious side effects. Since 2011, spending on this category of specialty medications has steadily increased.[10]

In 1990, only 10 FDA-approved drugs were considered to be specialty medications. By 2012, there were almost 300 specialty medications.[2,5]

Other Chronic Conditions

Various chronic conditions — from severe asthma to bleeding disorders such as hemophilia — are also managed by specialty medications. Due to the high cost of medications for rare diseases like cystic fibrosis and inherited genetic conditions, many of these drugs are also considered specialty products. Nearly half of novel drug approvals in 2015 were for rare diseases.[11]

Managing Specialty Spending: The NPS Strategy

NPS developed a multi-faceted approach to efficiently manage specialty drug spending. The components of the NPS strategy encompass utilization management, formulary management, benefit design management, specialty pharmacy partnership, and site of care management. All of these components allow for an integrated approach to control spending while allowing access to needed medications.

Utilization Management

Includes management tools such as prior authorization and quantity limits.

- Prior Authorization: Ensures clinically appropriate use of medications supported by FDA-approved indications and clinical literature.
- Quantity Limits: Encourages safe and appropriate use; helps reduce waste.

Formulary Management

The formulary is an approved list of medications prescription benefit plans use to achieve rational, cost-effective drug therapy.

Preferred Products

Products determined to be both clinically appropriate and cost-effective; these medications usually have a lower cost to the patient to incentivize use. These products may include copycats of brand name products (generics) or highly similar biologic products (biosimilars).

Benefit Design Management

Further encourages the use of preferred products via specialty tiers (such as tier 1 – generics; tier 2 – preferred brands; tier 3 – non-preferred brands; tier 4 – preferred specialty; tier 5 – non-preferred specialty)

Specialty Pharmacy Partnership

These pharmacies specifically dispense specialty pharmaceutical products and provide additional services to patients, such as monitoring for side effects, training on administration of injectable drugs, and support for adherence.

Site of Care Management

Specialty medications can be covered under the pharmacy benefit or the medical benefit.

- Pharmacy benefit sites of care include retail pharmacies, home delivery

pharmacies, and specialty pharmacies.

- Medical benefit sites of care include the physician's office, home infusion, infusion clinics, outpatient hospitals, and inpatient hospitals.

NPS actively manages high drug costs, reviewing new generics and new biosimilar products and incorporating cost-saving strategies as appropriate. For example, the biosimilar, Zarxio® (filgrastim-sndz) was added to the standard NPS formularies and integrated into utilization management protocols as clinically appropriate. In addition, NPS has developed a multi-level approach to managing chronic hepatitis C virus (HCV) medications, which includes the use of prior authorization and quantity limits to encourage appropriate utilization and reduce waste.

Future Outlook

Prescription drug spending is not anticipated to decrease in the near future — over 2,320 novel therapeutic products are in the late phase pipeline. The areas of oncology, neurology, and dermatology have the greatest number of products in development, further demonstrating the need for properly managed specialty drug spending.[18] One expert report has predicted healthcare spending in 2017 will increase only by the same amount as in 2016, as price increases are expected to be offset by an uptake in aggressive pharmacy benefit management negotiations (such as pay-for-performance reimbursement) and a plateau in the approval of blockbuster drugs (e,g., hepatitis C medications).[19, 20]

Regardless of predicted trends, specialty pharmaceutical products are here to stay, and proactive solutions are the cornerstone for controlling cost.

References

1. IMS Health Study: U.S. Drug Spending Growth Reaches 8.5% in 2015. Available at: http://www.imshealth.com/en/about-us/news/ims-health-study-us-drug-spending-growth-reaches-8.5-percent-in-2015. Updated April 14, 2016. Accessed September 14, 2016.
2. Penington R, Stubbings JA. Evaluation of specialty drug price trends using retrospective pharmacy sales transactions. J Manag Care Spec Pharm. 2016; 22(9):1010-17.
3. Concept Series Paper on Specialty Pharmaceuticals. Academy of Managed Care Pharmacy. Available at: http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=9305. Updated 2006. Accessed 2016.
4. AMCP Prepares Detailed Summary of CMS 2017 Draft Call Letter. Academy of Managed Care Pharmacy. Available at: http://www.amcp.org/Newsletter.aspx?id=20763. Updated February 24, 2016. Accessed September 22, 2016.
5. The Growing Cost of Specialty Pharmacy – Is it Sustainable? AJMC.com. Available at: http://www.ajmc.com/payer-perspectives/0213/The-Growing-Cost-of-Specialty-PharmacyIs-it-Sustainable. Updated February 18, 2013. Accessed September 21, 2016.
6. Diplomat Publishes New Report on Specialty Drugs Approved in 2015 and Expected for 2016. PR Newswire. Available at: http://www.prnewswire.com/news-releases/diplomat-publishes-new-report-on-specialty-drugs-approved-in-2015-and-expected-for-2016-300200604.html. Updated January 6, 2016. Accessed September 14, 2016.
7. Wasserman E. Specialty-drug spending set for double-digit leaps over the next 3 years: Express Scripts. FiercePharma. Available at: http://www.fiercepharma.com/financials/specialty-drug-spending-set-for-double-digit-leaps-over-next-3-years-express-scripts. Updated March 15, 2016. Accessed September 19, 2016.
8. Roddick J. Autoimmune Disease. Healthline. Available at: http://www.healthline.com/health/autoimmune-disorders. Updated July 22, 2015. Accessed September 19, 2016.
9. Rosman Z, Shoenfeld Y, Zandman-Goddard G. Biologic therapy for autoimmune diseases: an update. BMC Med. 2013; 11:88. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3616818/.
10. IMS Health. Spending on specialty medicines in 2015 increased 21.5% to $150.8 billion on an invoice price basis. Major Market Segments, National Sales Perspectives. Available at: http://www.imshealth.com/files/web/IMSH%20Institute/Reports/Medicines-Use-and-Spending-in-the-US-2015-to-2020/Spending_on_Specialty_Medicines.pdf. Updated January 2016. Accessed September 14, 2016.
11. Novel Drugs Summary 2015. U.S. Food & Drug Administration. Available at: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/ucm474696.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery. Updated January 2016. Accessed September 14, 2016.
12. List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools). U.S. Food and Drug Administration. Available at: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/

InVitroDiagnostics/ucm301431.htm. Updated June 9, 2016. Accessed September 21, 2016.
13. Lenvima (lenvatinib), Venclexta (venetoclax), Lynparza (olaparib), Odomzo (sonidegib), Tagrisso (osimertinib), Alecensa (alectinib) monographs. Lexicomp [online database]. Hudson, OH. Wolters Kluwer Health. Available at: http://online.lexi.com. Accessed September 21, 2016.
14. Franciscus A. A Brief History of Hepatitis C. HCSP Fact Sheet. Available at: http://hcvadvocate.org/hepatitis/factsheets_pdf/Brief_History_HCV.pdf. Updated March 2016. Accessed September 20, 2016.
15. Olek MJ. Disease-modifying treatment of relapsing-remitting multiple sclerosis in adults. UpToDate. Available at: www.uptodate.com [subscription required]. Updated July 15, 2016. Accessed September 20, 2016.
16. Patient education: Multiple Sclerosis in adults (The Basics). UpToDate. Available at: www.uptodate.com [subscription required]. Accessed September 20, 2016.
17. Kahn A. Bleeding Disorders. Healthline. Available at: http://www.healthline.com/health/bleeding-disorders#Overview1. Updated December 3 2015. Accessed September 19, 2016.
18. The late phase R&D pipeline remains robust and will ensure an ongoing high number of new brand launches by 2020, especially cancer treatments. IMS Health. Available at: http://www.imshealth.com/files/web/IMSH%20Institute/Reports/Medicines-Use-and-Spending-in-the-US-2015-to-2020/R&D_Pipeline.pdf. Updated April 2016. Accessed September 20, 2016.
19. Sagonowsky E. PBM hardball, specialty med slowdown to curb 2017 healthcare spending jump. FiercePharma. Available at: http://www.fiercepharma.com/pharma/specialty-drugs-loosening-their-grip-as-healthcare-spending-growth-expected-to-flatten. Updated June 21, 2016. Accessed September 21, 2016.
20. PwC. Behind the Number 2017. PwC Health Research Institute. Available at: http://www.pwc.com/us/en/health-industries/health-research-institute/behind-the-numbers.html. Updated 2016. Accessed September 21, 2016.
21. Fassbender M. Big pharma interest in specialty drugs will fuel US market growth says IMS Health. In-Pharma Technologist.com. Available at: http://www.in-pharmatechnologist.com/Regulatory-Safety/Big-pharma-interest-in-specialty-drugs-will-fuel-US-market-growth-says-IMS-Health. Updated March 17, 2016. Accessed September 21, 2016.

National Pharmaceutical Services (NPS) is a fully integrated pharmacy benefit manager (PBM) servicing Group and Commercial Health, Medicare Part D, Managed Medicaid, Health Insurance Exchanges, and Workers' Compensation programs.

NPS combines a client-oriented approach with a proprietary claims processing system to manage prescription drug costs and ensure appropriate care for members nationwide.

www.pti-nps.com

(800) 546-5677

PO Box 407, Boys Town, NE 68010