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California Pharmacist 2017
A peer-reviewed publication of the California Pharmacists Association

REVIEW

Specialty Pharmaceuticals – The New Frontier

By Craig S. Stern, RPh, PharmD, MBA, FASCP, FASHP, FICA, FLMI, FAMCP, FCPhA, CSP

ARTICLE HISTORY
Published: January 2017

Specialty medications, both injectable and oral, have gained significant interest due to their cost. Yet cost is only one factor. Specialty medications have moved into chronic therapy from their original position as treatments for rare and "orphan" diseases that affect very few patients. Specialty medications are replacing older small-molecule medications, primarily in treatments for cancer, blood diseases, and rheumatoid arthritis. In addition, new entrants are providing treatment options for multiple sclerosis, hepatitis C, diabetes, and HIV/AIDS that improve patient lives and provide a level of effectiveness that was previously unattainable. This article will address the specialty space, definitions and coding issues, methods for evaluation, pricing/payment, and context. Our goal is to understand these agents in the context of their definitions and the resulting impact on providers and payers.

Definitions

There is a general concern that specialty pharmaceuticals are an undefined category. They don't fit neatly into categories such as brand vs. generic, injectable vs. oral, location of service or other neatly defined categories. However, the alternative argument is that there are too many definitions, making it hard to characterize specialty pharmaceuticals under any one category. For example, specialty pharmaceuticals may be defined in the following ways:

- All injectables, self- or provider administered
- Facility administration or specialty pharmacy distribution
- Medicare Part B or D covered medications
- Medication cost greater than $600 (or some other threshold) per dose
- Special handling restrictions for distribution (e.g., refrigeration)

Consistent with the elements above, HealthInsurance.com defines specialty drugs as "high-cost prescription medications used to treat complex, chronic conditions like cancer, rheumatoid arthritis, and multiple sclerosis. Specialty drugs often require special handling (like refrigeration during shipping) and administration (such as injection or infusion)."

Each of the above definitions has limitations. For example, specialty pharmaceuticals include oral cancer chemotherapy as well as injectables. Medicare Part B contains enteral feeding, HIV/AIDS, diabetic testing, disposable medical equipment (DME), and radio-labeled diagnostics that may or may not be included in the specialty pharmacy scope or benefit. Specialty pharmaceuticals may also be dispensed by the retail network of pharmacies, and mail-service facilities, as well as specialty pharmacies. [Table 1]

The bottom line is that specialty pharmaceuticals are whatever the patient's insurance benefit covers and include those medications covered by limitations as defined by precertification criteria.

Coding – Medical Vs Pharmacy

A major source of confusion and complication is that specialty medications are defined, billed, and priced differently by medical and pharmacy benefits. Pharmacy traditionally defines medication by package and bills for the dispensed quantity. Medical benefits, on the other hand, define specialty medications by those medications covered by Medicare and quantities as doses or fractions of a dose. To further complicate the definition of medications under Medicare, drugs are covered under two categories, Level I and II, composed of multiple codes. [Table 2]

- Level I: Common Procedure Coding (CPT) codes are referred to as Level I codes and are maintained by the American Medical Association (AMA). Level I codes are five (5) characters in length and are numerical (e.g., 99211, 30520, etc.). CPTs cover services and procedures furnished by physicians and health-care professionals.
- Level II: Healthcare Common Procedure Coding System (HCPCS) codes are referred to as Level II codes and are governed by the American Hospital Association (AHA) and the Center for Medicare and Medicaid Services (CMS). Level II codes are five (5) characters in length and are composed of one (1) letter and four (4) numbers (e.g., J1950, J9217, etc.). HCPCS cover products, supplies, and services furnished outside of physician's offices, and DMEPOS (DME, prosthetics, orthotics, and supplies).[1]

In addition to medication-specific codes, medical billing and payments include multiple other codes to cover every element of the patient care experience. Many of these codes are common to both medical and pharmacy. [Table 3] These additional codes include:

- Administrative Codes – separate codes for administration of the medication, especially vaccines
- Place of Service Codes – two-digit codes required for the actual place where service is provided (e.g., the pharmacy place of service code is 01)
- Provider Codes, also known as Medicare Specialty Codes – represent the types of providers and suppliers who are eligible to apply for enrollment in the Medicare program – these codes link to the Healthcare Provider Taxonomy Codes (www.wpc-edi.com) and are maintained by the National Uniform Claim Committee (www.nucc.org)
- Revenue Codes – Revenue Codes are descriptions and dollar amounts charged for hospital services provided to a patient. Their purpose is to group the same services for simplification and improved transparency of the coding process. The revenue code tells an insurance company whether the procedure was performed in the emergency room, operating room, or another department. These codes are also used by some insurers for outpatient claims, e.g., code 0250 is pharmacy general.[2]

Specialty Space

Specialty medications are provided through medical and pharmacy subchannels, which makes the space very competitive and at the same time diverse. [Table 1] Pharmacy subchannels are dominated by specialty pharmacies that dispense medications to homebound patients. Medical subchannels are more diverse in that specialty medications are administered in physician offices, multispecialty clinics, oncology clinics, acute care hospitals, emergency medicine, etc. As a result, competition for patient business is not only competitive between medical and pharmacy channels, but also very competitive between medical subchannels, and soon between specialty pharmacies and retail network pharmacies. This competition has produced a commercial emphasis on "site-of-care optimization," where pharmacy channels are attempting to move product sourcing and delivery from medical channels to pharmacy delivery and mail-type service.

Specialty Benefits And Contracting

Medications were originally covered as riders to comprehensive medical benefits, but with the advent of managed care, they took a larger share of ambulatory practice that required broader benefit designs. These designs were anchored by formularies that moved from open, closed, and other restrictive models to tier-based designs that placed emphasis on the choices among various options within therapeutic categories. Elements of Medicare Part D, price competition, and manufacturer cost offsets, e.g., rebates, provided additional options to add to pharmaceutical benefit models.

Specialty medications have added yet another dimension. These medications treat previously untreatable conditions as well as replacing current treatments for common chronic conditions. These conditions are often severe and have complicated courses. Specialty medications further complicate patient care because of their molecular size, requiring special handling; complicated mechanisms of action, requiring enhanced testing; and toxicity, which adds to patient discomfort as well as needing to be managed by a team of healthcare professionals. And then there is the cost.

Pharmacy benefits have had to develop a dynamic posture in order to keep up with rapid developments in the specialty arena. This posture has led to formulary expansion to incorporate the new agents, integration of coverage for medications covered under medical benefits separate from pharmacy benefits, and channel requirements for distribution and administration. Among these, integration of medical and pharmacy benefits is a relatively new problem, because there was little prior need to be concerned with the overlap of medications covered under each benefit. Generally, medical benefits covered injectables administered by physicians and nurses. Pharmacy benefits covered medications dispensed by pharmacies to patients who self-administered. The merging of benefits for medications that might be delivered and administered under either benefit places a special emphasis on coding definitions, channel competition, and purchaser-provider contract language.

The primary elements for benefits and resulting purchaser-provider contracts reflect the new reality of merging medical and pharmacy benefits. These elements are driving provider competition for patients and expanding the dynamic of how drugs are categorized. To summarize the landscape of this new perspective on therapy, consider the following:

- Dynamics of specialty introductions and expansion of covered indications
- Specialty coverage implemented through coding definitions (Level I or II)
- Categorization coding for therapeutic similarity (previously brand vs. generic)
- Channel variation and competition, including medical and pharmacy subchannels
- Preferred provider vs. nonexclusive agreements
- Bases of cost complicated by the movement of traditional average wholesale price (AWP) to wholesale acquisition cost (WAC), maximum allowable cost (MAC), average acquisition cost (AAC), national average drug acquisition cost (NADAC), average sales price (ASP), and average manufacturers' price (AMP).[3]
- Coding options (e.g., J-Code description of unit vs. package unit), including special use codes (e.g., miscellaneous dump, not otherwise classified – NOC/NOS)

Blood and blood derivatives are a special case. Blood factor billing codes depend on the provider type. Pharmacists must bill using the National Drug Codes (NDC). All other providers must bill according to physician-administered drug policy, CMS-1500 Billing Instructions, Physician-Administered Drugs – NDC, or UB-04 Billing Instructions. Reimbursement for blood factors is based on the lesser of the average sales price (ASP) plus 20% or the provider's usual and customary charges (U&C).

Another special case is coagulation factors for bleeding disorders, e.g., hemophilia. These factors represent the first class of specialty medications that utilize provider contracts. The provider should refer to the codes for each state. As an example of the types of obligations required under these contracts, consider the California W&I Code:

"The Department of Health Care Services (DHCS) will contract with any specialty pharmacy that will sign a contract to meet a list of performance obligations. These include, but are not limited to,

delivery time requirements, providing patient education, and submitting quarterly and yearly reports to DHCS."[4]

Specialty Billing

Since HCPCS and CPT coding is central to definitions, locations of administration, claim administration, and payment of specialty medications, it is important to understand the elements of medical claims and how they differ from pharmacy claims administration. [Table 3, Table 4 for data vendors]

The primary elements of a claim are similar for both medical and pharmacy claims; namely, patient, doctor, medication, and date of service. The primary difference is the NDC of the medication and the quantity administered or dispensed. While pharmacy claims must include NDC, historically, medical claims have not. Also, the quantity dispensed by the pharmacy is not the same as the quantity provided in the medical claim that is a multiple of the HCPCS-defined unit of dosage. All of this changed when Medicaid and Medicare issued reporting and billing requirements that mandate elements in medical claims that have interfered with accurate submissions. These requirements apply to specific circumstances, but they are being applied broadly. The requirements are, in summary:

- Medicaid Reporting Requirements are part of the Deficit Reduction Act (DRA) 2005, Section 6002, with added provisions under Section 1927. The states are directed to require physicians in their offices and hospital outpatient settings or other entities (e.g., nonprofit facilities) to collect and submit the drug NDC numbers on Medicaid claims to their state. These requirements are effective January 1, 2008, and Section 1927(a)(7)(B)(ii) of DRA eliminates federal financial participation (FFP) when states fail to collect NDCs.
- Medicare Billing Requirements apply to physician billing offices, hospital outpatient departments, and outpatient clinic billing offices. They apply to dual eligibles, i.e., patients who are eligible for both Medicare and Medicaid benefits, who received physician-administered drugs as part of the medical encounter. The requirements cover bills for physician-administered drugs on claims to Medicare containing:
  - o HCPCS (e.g., J-code) in 2400 SV202-2, with SV202-1=HC
  - o Each Part B drug HCPCS reported in 2400 SV202-2, complete the required associated 2410 LIN and CPT04 segments with[5]:
    - NDC in 2410 LIN03, with LIN02=N4
    - Quantity/unit (including fractional units) count in 2410 CPT04
    - Unit of measure (IU, gm, ml, unit) in 2410 CPT05 and CPT05-1

Wastage – Waste Not, Want Not, But What To Bill?

The disparity between HCPCS units and commercial packaging has led to a problem for all providers; namely, what to do with the medication remaining in the bottle that was not administered. This is a very common problem and poses a compensation problem for physicians, hospitals, and pharmacies.

CMS has addressed this issue in Regulations and Guidance 100.2.9 - Submission of Claims with the Modifier JW, "Drug Amount Discarded/Not Administered to Any Patient."[6]

If the physician, rather than the patient and/or a facility, supplies the drug and must waste some portion in the vial that is not administered, Medicare may allow compensation for this wasted portion. The National Medicare guidelines for reporting drug waste are included in the Claims Processing Manual, chapter 17, § 40.0. The instructions are to report wastage in addition to the drug administered. The appropriate HCPCS Level II supply code must be used to list the drug administered with the correct number of units in box 24D of the CMS-1500 claim form. The number of wasted units is reported as a second line item. Provider documentation must verify the exact dosage of the drug injected and the exact amount and reason for any waste as indicated below:

Caution: "The JW modifier must not be used on Medicare Part B Drug CAP claims (The Competitive Acquisition Program); providers shall not code for wastage for drugs furnished under the CAP. Claims for drugs provided under CAP submitted with the JW modifier will be treated as unprocessable."

(Rev. 1313; Issued: 07-23-07; Effective/ Implementation Date: 08-23-07)

Medicare contractors generally require that the JW modifier is appended to the drug or biological amount discarded/ not administered to identify an unused drug from single-use vials or single-use packages that are appropriately discarded. The emphasis is that Medicare will reimburse only for drugs supplied in single-use vials, and CMS officially encourages "physicians, hospitals, and other providers to schedule patients in such a way that they can use drugs or biologicals most efficiently, in a clinically appropriate manner."

Examples

1. From a single-use vial that is labeled to contain 100 units, 90 units are administered to the patient and 10 units are discarded. The 90-unit dose is billed on one line, and the 10 discarded units are billed on another line with modifier JW. Both line items would be processed for payment.
2. If the actual dose of the drug or biological administered is less than the billing unit, then the JW identifier cannot be used. "For example," the Claims Processing Manual advises, "one billing unit for a drug is equal to 10 mg of the drug in a single-use vial. A 7 mg dose is administered to a patient, while 3 mg of the remaining drug is discarded. The 7 mg dose is billed using one billing unit that represents 10 mg on a single line item. The single line item of 1 unit would be processed for payment of the total 10 mg of drug administered and discarded. Billing another unit on a separate line item with the JW modifier for the discarded 3 mg of drug is not permitted because it would result in overpayment. When the billing unit is equal to or greater than the total actual dose that was administered and the amount discarded, the use of the JW modifier is not permitted."

Caution: Unique billing rules apply when reporting discarded erythropoietin stimulating agents for home dialysis. See the Medicare Claims Processing Manual, chapter 17, § 40.1 for more details.[7]

Biosimilars

Reminiscent of the movement to produce generics that are cheaper than their branded counterparts, now comes the introduction of biosimilars to compete with their pioneer biologicals. There is also the companion concept of "bio-betters," for which there is no currently marketed product, but which represent a drive to improve on the pioneer specialty biological. Multiple decisions currently block clear substitution for cheaper products, not the least of which are naming, coding, and legislative hurdles. However, the larger issue is that the selection of biosimilars, or even bio-betters, presents new decision problems for prescribers and pharmacists; namely, are biosimilars equal in clinical effectiveness to the pioneer biological, and are they similar in risk? With brands and generics, the same active ingredient is being compared for substitution. With biosimilars, there is a clinical decision to be made that requires both the physician and the pharmacist to know and understand the literature, pharmacology, and adverse drug reactions for patient subpopulations at risk. Some of this risk is assumed by health plans through restricted formularies, NDC blocks, step therapy, and prior authorizations. REMS requirements will shield prescribers and pharmacists from some risk, but nothing will be a substitute for study and knowledge of these products. This is the subject of a discussion of utilization management that will be addressed in a separate article. However, as state laws allowing for substitution continue to change, much of the weight of the biosimilar substitution will fall on pharmacists.

For further information, consider "State Laws and Legislation Related to Biologic Medications and Substitution of Biosimilars," which examines both state and federal substitution policies, with citations for enacted and proposed laws and regulations, from the National Conference of State Legislatures.[8]

The Future

The immediate future is already defined by common digital vocabularies to allow communication between various stakeholders, evidence-based health information as a basis for decision making, the movement from managed care to population health monitoring, and the integration of pharmacy claims/medical encounter/laboratory value and biometric screening data leading to data-based decision making. The resulting incorporation of medication therapy management (MTM), medical encounters stored in electronic medical records (EMRs), and biometric screening is already leading to the expansion of population healthcare management and the impact of patient influence on decision making.

All of this integration impacts specialty medications treating more complicated conditions with medications that provide expanded options and greater risks. An educated provider team will be critical to manage the care of the population covered by specialty medications. In that regard, specialty medications are driving medicine away from art to more data-based, evidence-based scientific care.

About the Author

Craig S. Stern, PharmD, MBA, is the president of Pro Pharma Pharmaceutical Consultants in Chatsworth, CA, and a professor pharmacy at the University of Southern California, University of California, San Francisco and Western University of Health Sciences. He is a fellow of the Academy of Managed Care Pharmacy, the American Society of Consultant Pharmacists and the American Society of Health-System Pharmacists. Conflict of Interest Disclosure: None reported.

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8. http://www.ncsl.org/research/health/state-laws-and-legislation-related-to-biologic-medications-and-substitution-of-biosimilars.aspx

Table 1: Specialty Locations Of Service

Medical Subchannels	Pharmacy Subchannels
• Ambulatory Clinics • Emergency Medicine • Home Care • Infusion Centers • Inpatient Hospital • Outpatient Hospital • Physician's Office • Surgery Centers	• PBMs • Retail Pharmacy Network • Specialty Pharmacies

Table 2: Specialty Code Categories

Code	Scope
A	Emergent and nonemergent transportation services; miscellaneous medical and surgical supplies, including dressings, ostomy and urinary supplies, and some diabetic and DME supplies; also includes radiopharmaceutical diagnostic agents.
B	Enteral and parenteral therapy, including codes for supplies, formulae, nutritional solutions, and infusion pumps.
C	Temporary codes for use with Outpatient PPS (Prospective Payment System). C-Codes are used exclusively to report services, drugs, biologicals, and devices eligible for transitional pass-through payments for hospitals, and for items classified in new-technology ambulatory payment classifications (APCs) under the Outpatient PPS (Prospective Payment System). They may not be used to bill under other Medicare payment systems.
J	Permanent codes used to report injectable drugs that ordinarily cannot be self-administered: chemotherapy, immunosuppressive drugs, and inhalation solutions, as well as some orally administered drugs. Drugs and biologicals are usually covered by Medicare if: • they are of the type that cannot be self-administered • they are not excluded, i.e., immunizations • they are reasonable and necessary for the diagnosis or treatment of the illness or injury for which they are administered • they have not been determined by the FDA to be less than effective In addition, they must meet all the general requirements for coverage of items as incident to a physician's services. Generally, prescription and nonprescription drugs and biologicals purchased by or dispensed to a patient are not covered.
P	Pathology and laboratory services codes. P-Codes are used for reporting chemistry, toxicology, microbiology, and pathology screening tests (e.g., PAP), as well as blood-related products.
Q	Temporary codes. Q-Codes are used for casting procedures, services, and supplies. If a permanent code is subsequently assigned (J-Code), the Q-Code is deleted and cross-referenced.
S	Temporary national codes (non-Medicare). S-Codes were developed by Blue Cross/Blue Shield and other commercial payors to report drugs, services, and supplies. They may not be used to bill services paid under any Medicare payment system.
CPT® Coding for Immune Globulins, Vaccines, and Toxoids	CPT®-Codes (Current Procedural Terminology) are assigned by the AMA and used to bill for immune globulins, vaccines, and toxoids. Immune Globulins: Products listed include broad-spectrum and anti-infective immune globulins, antitoxins, and various isoantibodies. Vaccines/Toxoids: Multiple codes for a particular vaccine/toxoid are provided when the schedule (number of doses or timing) differs for two or more products of the same vaccine type (e.g., hepatitis A, HiB) or the vaccine product is available in more than one chemical formulation, dosage, or route of administration. Separate codes are available for combination vaccines (e.g., DTP-Hib, DtaP-Hib, and HepB-Hib). It is inappropriate to code each component of a combination vaccine separately. If a specific vaccine, toxoid, or immune globulin code is not available, the unlisted CPT® code 90749 (vaccines/toxoids) or 90399 (immune globulins) should be reported until a new code becomes available.
WW	For DMERC Level III oral anti-cancer drugs. WW-Codes are for DMERC internal systems processing only. Providers should still bill using the appropriate NDC number for the oral anti-cancer drug utilized. Each WW Code has a specific NDC number that represents the drug name and strength. DMERC will be reimbursed based on this information.

Reference: http://www.j-codes.com/

Table 3: Elements Of Medical/Pharmacy Claims

Medical	Pharmacy
HCPCS and CPT drug-specific codes – • Many NDC to each code • Many codes per NDC	NDC
Dose or fraction of a dose	Included in Sig – Quantity/Days' Supply
HCPCS unit	Quantity Dispensed
Date of service – single or range for institutional / hospital stays	Date of Service of Dispensing
Date range of duration of care – often missing	Days' Supply
Prescriber ID – NPI for individual NPI for group or practice site Tax ID (historical)	Prescriber NPI
Location of Service (POV, hospital, clinic, EM, etc.)	Dispensing Pharmacy

Table 4: Sample Of Data Vendors (Data From Vendor Webpages)

VENDOR	FEATURES
First Data Bank HCPCS Select™	NDC/HCPCS, pricing link – WAC/SWP/ASP/PAL, Part B
Medi-Span/Wolters Kluwer	All HCPCS values, map to NDC/UPC/HRI, Qty map
Manufacturers	Lists of NDCs and HCPCS Codes
Noridian Admin Services	NDC/HCPCS crosswalk
NovoLogix	NDC/HCPCS crosswalk
J Code Calculator™/Pro Pharma	NDC/HCPCS crosswalk, Unit/Package calc., AWP/WAC/ASP/NADAC/AAC/MAC, Brand/Generic, Part B/D, Therapeutic Class, ICD9/ICD10, Qty map, Usage Map
RJ Health Systems	NDC/HCPCS crosswalk, CPT, ICD9, Therapeutic Class, pricing – AWP, WAC, ASP, APC
Red Book/Truven/IBM	NDC, HCFA J-Codes, AWP/WAC, Brand/Generic

http://www.fdbhealth.com/fdb-medknowledge-clinical-modules/medicare-hcpcs-select/
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