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# Vizient Focus Group: 505(b)(2) Approved Medications

February 2025

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# Introduction

The 505(b)(2) New Drug Application (NDA) approval pathway enables pharmaceutical manufacturers to expedite drug development by leveraging existing research, reducing the need for duplicative studies compared to the 505(b)(1) pathway.[1] The manufacturer requesting approval via the 505(b)(2) pathway is allowed to submit data originally collected by another researcher or manufacturer.

Drugs approved via the 505(b)(2) pathway are not generic molecules of the reference listed drug (RLD) and can differ in characteristics like dosage form, strength, route of administration, formulation (including excipients), dosing regimen, active ingredient (e.g., different salt or enantiomer), reconstitution or compounding instructions, or indication (new use for an existing drug). They may have similar clinical effects and the same place in therapy as an RLD, but most products are not proactively reviewed by the Food and Drug Administration (FDA) for therapeutic equivalence (TE) at the time of approval.

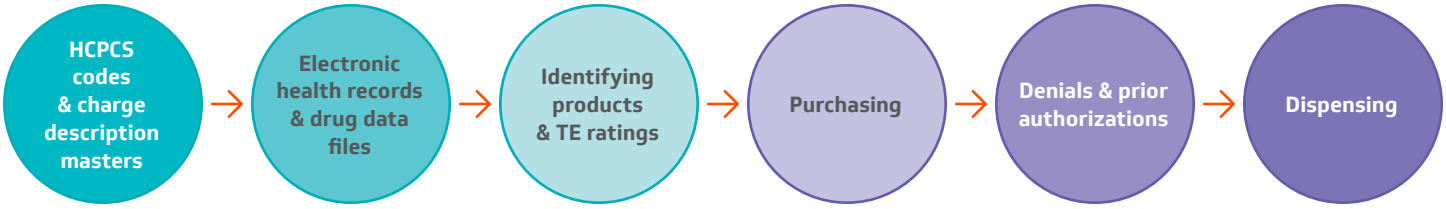
In the 3rd quarter of the 2022 Healthcare Common Procedure Coding System (HCPCS) coding cycle, the Centers for Medicare & Medicaid Services (CMS) reviewed its approach for establishing HCPCS Level II codes for products approved after October 2003 under the 505(b)(2) NDA or the Biologics License Application (BLA) pathways that lack a therapeutic equivalence rating to a RLD with an existing code.[2]

To address the financial and operational challenges resulting from these coding changes, Vizient® convened a focus group comprising 57 subject matter experts in pharmacy revenue cycle, informatics, workflow management, formulary management, and procurement and inventory management from 40 hospitals and health systems. The primary objectives of the focus group were:

- To identify the roles of various key stakeholders and the impact of 505(b)(2) approved medications on pharmacy revenue and workflow processes.
- To develop supportive educational materials for managing 505(b)(2) approved medications.
- To address challenges and advocate for change with the goal to reduce the financial and operational burdens on dispensing pharmacies and revenue cycle teams.

Through participant surveys and virtual meetings, the group selected 6 key focus areas for discussion and analysis (Fig. 1).

**Figure 1. Focus Group Topics**



Discussions on these topics revealed potential risks, including purchasing errors, incorrect product selection, compounding and administration errors, unintended therapeutic substitutions, incorrect medication record file builds, an inaccurate charge description master (CDM), and denied claims – all of which can lead to increased workload and financial losses. The focus group further identified key practice considerations for managing 505(b)(2) approved products and proposed proactive initiatives for improvement.

## Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (also known as the Hatch-Waxman Amendments) added sections 505(b)(2) and 505(j) to the Federal Food, Drug, and Cosmetic Act (FD&C Act), to establish streamlined processes for obtaining approval of NDAs and abbreviated new drug applications (ANDAs).[3] Since 2015, NDAs approved through the 505(b)(2) pathway have comprised approximately 50% of all NDAs submitted annually.[4]

**Table 1. 2015 – 2023 Calendar Year 505(b)(2) NDA Approvals**

| Year | Total NDA Approvals | 505(b)(2) Approvals | Other Approvals | %505(b)(2) |
|---|---|---|---|---|
| 2023 | 112 | 58 | 54 | 52% |
| 2022 | 93 | 59 | 34 | 63% |
| 2021 | 102 | 50 | 52 | 49% |
| 2020 | 114 | 62 | 52 | 54% |
| 2019 | 106 | 55 | 51 | 52% |
| 2018 | 124 | 60 | 64 | 48% |
| 2017 | 126 | 73 | 53 | 58% |
| 2016 | 86 | 43 | 43 | 50% |
| 2015 | 109 | 49 | 60 | 45% |
| **TOTAL** | **972** | **509** | **463** | **52%** |

## What's new?

Prior to January 2023, the Centers for Medicare & Medicaid Services (CMS) frequently assigned drugs approved via the 505(b)(2) pathway to the same Healthcare Common Procedure Coding System (HCPCS) code as the RLD and its generics. However, to align with the broader approach used for assigning HCPCS codes to products reimbursed under Section 1847A of the Social Security Act (the Act), CMS clarified existing policies and implemented several coding changes, effective January 1, 2023.[2]

- 505(b)(2) products are approved under separate NDAs and are considered single source drugs when not rated as TE to a RLD in the FDA's Orange Book.[5]
- For all products considered single source drugs, including those approved via the 505(b)(2) pathway, there is a programmatic need for each product to have a unique manufacturer-specific HCPCS code with payment based on that specific manufacturer's Average Sales Price (ASP).
- Products that meet the statutory definition of a generic drug and are rated as TE in the FDA's Orange Book are considered by CMS to be a multiple source drug and share a HCPCS code with the RLD and any other approved generics.

### Table 2. Types of New Drug Applications

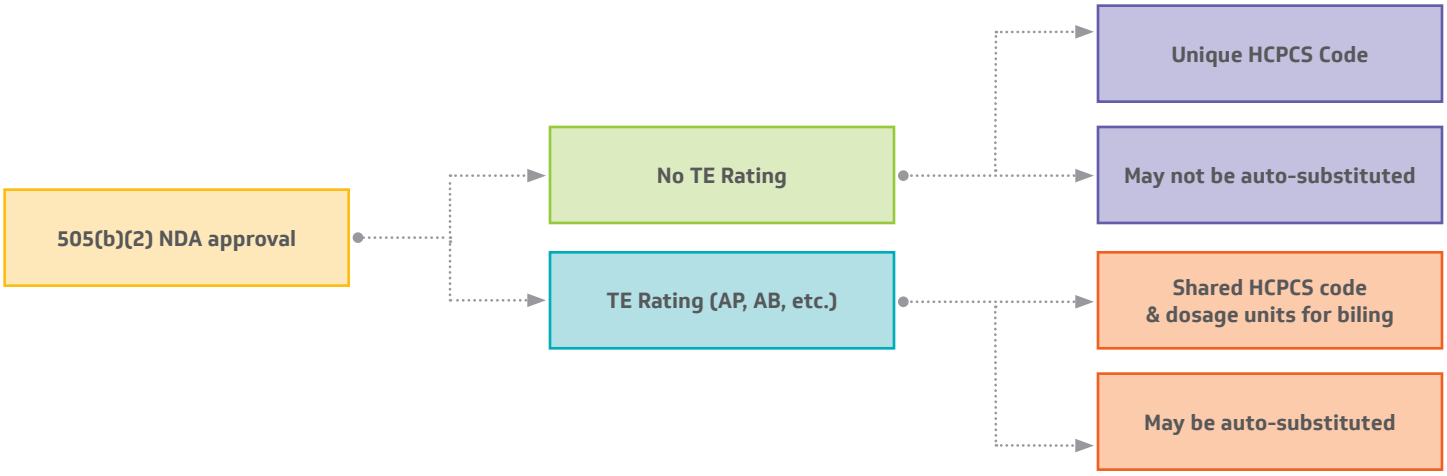
| Approval Type | Product | Description | HCPCS code Assignment | Example |
|---|---|---|---|---|
| NDA 505(b)(1) | "Stand-alone" (usually RLD) | NDA that contains full reports of investigations of safety and effectiveness | Manufacturer specific | Bortezomib (Velcade) J9041 |
| NDA 505(b)(2) | Different characteristics from RLD | NDA that contains full reports of investigations of safety and effectiveness but where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. | Manufacturer specific[a] | Bortezomib (Hospira) J9049 |
| ANDA 505(j) | Generic duplicate | ANDA that contains information to show that the proposed product is identical in active ingredient, dosage form, strength, route of administration, labeling, quality, performance characteristics, and intended use, among other things, to a previously approved product. | Same as RLD and any other approved generics | Bortezomib (Meitheal) J9041 |

[a] Unique to the manufacturer filing the NDA; any other labelers manufacturing under that NDA will share that HCPCS code.

- Effective January 1, 2023, CMS began assigning unique, manufacturer-specific HCPCS codes to products newly approved under the 505(b)(2) NDA pathway without a TE rating. Additionally, CMS started to reassign certain previously approved 505(b)(2) products without a TE rating to manufacturer-specific HCPCS codes.
- CMS also began removing brand names from the description of any existing HCPCS codes as needed (e.g., removal of "Velcade" from J9041).[2]

Although most 505(b)(2) approved products are not TE rated at the time of approval, FDA must evaluate TE for products intended for parenteral, ophthalmic, or otic use. Specifically, as provided in Section 3222 of the Food and Drug Omnibus Reform Act of 2022 ("FDORA"), FDA must evaluate TE no later than 180 days after approval, provided that the sponsor requested a TE evaluation and provided the necessary data. If the application was approved or submitted before FDORA was enacted, then FDA will complete the TE evaluation no later than 180 days after receipt of a request *by the applicant*.[6]

### Figure 2. CMS HCPCS assignments by TE Rating and Auto-substitution Status



# Focus group insights

## Identifying 505(b)(2) products and TE ratings

Focus group members agreed that 505(b)(2)-approved products are not easily identifiable. During discussions, the group further highlighted several key challenges in accurately determining whether a product has been approved via this pathway.

These challenges include:

- With the same naming convention as generic drugs and labeling similarities, 505(b)(2) products are often unknowingly mistaken as TE-rated approved generics.
- FDA does not maintain a comprehensive list of 505(b)(2)-approved products on its website. Identifying a product's approval pathway requires significant time and effort, as current methods require knowledge of the approval year or application number and sponsoring manufacturer.
- CMS does not proactively identify which products are 505(b)(2) approved or TE rated on the CMS ASP-HCPCS crosswalk or ASP pricing files. However, the HCPCS code description for 505(b)(2) products does include the name of the manufacturer who submitted the NDA.[7]
- Most wholesale distributors do not directly identify 505(b)(2) products on their purchasing portals. Some can be customized to provide the HCPCS code or TE rating, but the buyer must know what these indicators mean.

## HCPCS codes and charge description masters

When dispensing a 505(b)(2) approved product under the Medicare Outpatient Prospective Payment System (OPPS), the correct HCPCS code and an up-to-date charge description master (CDM) are essential for accurate billing and for reducing the number of denied claims. The focus group shared these concerns:

- CMS coding descriptions lack the necessary detail to confirm 505(b)(2) approval. Additionally, complexities arising from distribution licensing, private labeling, mergers, and acquisitions may result in discrepancies between the original FDA applicant and the labeler marketing the product. Consequently, the manufacturer listed in the HCPCS code description may not always align with the supplier on purchasing platforms, ordering systems, or product labeling. Furthermore, a single manufacturer may market both generic products and a 505(b)(2) product for the same drug, adding to the identification challenges.
- HCPCS codes may change. For instance, CMS is completing a retrospective review of previously approved 505(b)(2) products and reassigning them from a shared HCPCS code to a manufacturer-specific HCPCS code, provided the product lacks a TE rating and is considered a single source product.[3] Additionally, a 505(b)(2) product initially approved without a TE rating may later receive one following an FDA evaluation, such as upon a manufacturer's request for TE review. When a TE rating is assigned, the drug will no longer be considered a single source product and will no longer have its own unique HCPCS code.
- Although the ASP-HCPCS crosswalk and ASP pricing files are the most reliable resources for HCPCS code assignments and payment limits, there are sometimes inconsistencies with how HCPCS codes are assigned. The timing of the crosswalk – a quarterly publication - may not coincide with the approval of a 505(b)(2) product, which may be available for use before the HCPCS code has been added.
- Reference listed drugs with several generics and 505(b)(2) products have multiple HCPCS codes. The large number of quarterly HCPCS updates increases the risk for CDM inaccuracy and increases the workload for CDM maintenance. Errors in the CDM often go unnoticed until claims are denied.
- Management of this complex process requires crucial communication between key internal and external stakeholders such as the health system's finance, revenue cycle and prior authorizations teams, the pharmacy business team, pharmacy clinical and operations teams (buyers, operational pharmacists, compounding staff), clinical staff, IT (finance and pharmacy), patient financial services, and wholesale distributors.
- Fragmented oversight of the CDM can result in billing errors that may result in a significant increase in workload to resubmit denied claims and/or loss of reimbursement.

> **" Due to the complexity and nuanced nature of the differences between each product, we encourage providers to rely on the Average Sales Price (ASP) HCPCS-NDC crosswalk to identify the correct billing and payment code for each applicable product."**
>
> From: Centers for Medicare and Medicaid Services

## Electronic Health Records (EHR) and medication records

When drug databases send drug data files to pharmacy information systems, medications with the same route, dosage form, dose and active ingredients are consolidated into a single medication record. Many of the drug database algorithms assume that 505(b)(2) drugs are interchangeable like generic molecules. Because most pharmacy information systems allow multiple NDCs in a single medication record, the HCPCS code must be assigned at the NDC level.

- These challenges may result in the need to create different electronic medication entries in the pharmacy information system for each 505(b)(2) product rather than combining the NDCs of 505(b)(2) products into the shared medication record.
- If this approach is taken, drugs that previously had a single medication record – encompassing multiple NDCs from the RLD and its approved generics - may now be assigned separate medication records for each 505(b)(2) product, which makes product selection unclear for order-entry pharmacists. These separate records may require additional IT maintenance as the periodic drug database updates will attempt to override these unique records.
- This approach can also require a naming scheme to differentiate the 505(b)(2) products and signify groups of products that may be therapeutically equivalent.
- Management of this crucial step requires consistent communication between key stakeholders in health system and pharmacy informatics, the pharmacy business and purchasing teams, and the CDM team. If the medication record is not built or updated correctly, a 505(b)(2) product may be unknowingly auto-substituted for a RLD or its generic and may be billed to the wrong HCPCS code or may be billed under a different HCPCS code than what was approved during the prior authorization process.

## Purchasing

Recognizing that 505(b)(2) products differ from generics is necessary for informed purchasing decisions. A lack of awareness may lead to inadvertently purchasing non-TE rated 505(b)(2) products with distinct HCPCS codes, instead of selecting a TE-rated generic as intended.

- Recognizing 505(b)(2) products on the wholesale distributor portal can be difficult for buyers as most portals do not indicate the specific approval pathway.
- Some portals indicate the HCPCS code, providing buyers with an indication that a product is not a generic drug. However, CMS makes intermittent updates to the crosswalk throughout the quarter and the portals may not have the most current information. Others may include the TE rating.
- Some institutions may choose to block 505(b)(2) purchases and only purchase products with one shared HCPCS code. While this may be feasible on a case-by-case basis, it may not be practical for all organizations or all 505(b)(2) products. For example, shortage situations may require the utilization of 505(b)(2) products, some 505(b)(2) products may be required for rebates or other purchasing contract terms, and/or payers may require the administration of a specific 505(b)(2) product.
- Some 340B accumulations may pass over to the new NDC and require reaccumulating.
- Specific training for pharmacy buyers is required to know how to identify a 505(b)(2) product on the wholesale distributor portal and how to make an informed purchasing decision in alignment with the organization's policy or preferred product strategy.


## Denials and Prior Authorization

With all separately payable medications billed under Medicare OPPS, incorrectly assigned HCPCS codes can lead to denied claims, delayed reimbursement, and financial burdens for patients and health systems. The unique HCPCS code assignments for 505(b)(2) products introduce additional complexities, leading to increased challenges in claims processing. As outlined below, there are multiple reasons for claim denials.

- When a 505(b)(2) product is unknowingly dispensed in place of a generic and is billed to the generic HCPCS code or if the incorrect HCPCS code is assigned in the CDM, the claim may be denied.
- Also, when a 505(b)(2) product is unknowingly dispensed in place of another product that has been approved per prior authorization, the claim may be denied.
- The CMS crosswalk is updated quarterly and can also be updated intermittently throughout the quarter requiring continued vigilance to keep the CDM up-to-date and accurate.
- The prior authorization team often is not aware of which product will be dispensed in the pharmacy, and the pharmacy staff often is not aware of which NDC or HCPCS code was approved by the prior authorization team.
- There may be payer restrictions or preferences requiring specific NDCs or HCPCS codes.

## Dispensing and NDCs

Due to the same name and labeling of 505(b)(2)-approved products and 505(j)-approved generics, there is often nothing that physically distinguishes the products from each other on the shelf of the pharmacy. The two often look identical.

- The pharmacist often is not aware of which NDC or HCPCS code is authorized for use when verifying the medication order or which NDCs are assigned to a given code. There may not be a process in the pharmacy information system to direct the pharmacy compounding staff which NDC to dispense.
- The prior authorization team often is not aware of which NDCs are in inventory in the pharmacy, and tracking inventory is time consuming and difficult.
- Often there are no differentiating factors on the labels of 505(b)(2) products and generics for the pharmacy compounding staff to know the difference between them.
- Compounding instructions and infusion times for 505(b)(2) products may vary from generic products, potentially increasing the risk of compounding and administration errors if not carefully managed.

# Practice considerations

1. Enhance awareness and provide education to all relevant team members on 505(b)(2)-approved products, highlighting the unique differences and the challenges associated with dispensing these products.
2. Confirm 505(b)(2) approval on one of the following resources:
   a. FDA's NDA and BLA Calendar Year Approvals report for 505(b)(2) products approved prior to the current year. (The approval year is needed.)[4]
   b. FDA's Drugs@FDA: FDA-Approved Drugs webpage. (The drug name or active ingredient, and the application number or manufacturer who submitted the application is needed.)[8]
   c. The package inserts (PI) on DAILYMED. (The PI indicates NDA vs ANDA but does not specify if the NDA was submitted via the 505(b)(2) or 505(b)(1) pathway.)[9]
   d. A trusted third-party provider (often subscription based)
3. Review the CMS Quarterly ASP Pricing Files and CMS ASP-HCPCS crosswalk at the beginning of each quarter for new HCPCS codes and HCPCS changes. Review and reconcile updates on the CMS ASP Pricing Files webpage and utilize the current on-line version of the crosswalk (search by NDC) throughout the quarter for the most up-to-date HCPCS assignment information. Reach out to your Medicare Administrative Contractor (MAC) if unsure which HCPCS code to use or the NDC does not appear on the crosswalk.[10]
4. Sign up for the CMS HCPCS Level II Updates Listserv and for the Medicare Learning Network newsletters to get the most current and accurate information about HCPCS Level II codes.[11,12]
5. Establish a communication plan for sharing HCPCS code and NDC information with key stakeholders including finance, revenue cycle and prior authorizations teams, the pharmacy business team, pharmacy clinical and operations teams (buyers, order entry pharmacists, and compounding staff), clinical staff, IT (finance and pharmacy), patient financial services, and wholesale distributors:
   a. Provide direction to the buyers regarding which NDCs to buy and which to avoid.
   b. Establish a process for distributing HCPCS code updates for preferred agents to the appropriate clinical and prior authorization teams.
   c. Consider meeting with the wholesale distributor to determine any NDC/HCPCS code mismatches that may indicate a wrong product was purchased.
6. Establish a policy for shared pharmacy and revenue cycle oversight of the CDM. The policy should assign responsibilities and include a process for entering correct HCPCS code information by NDC in the CDM. Establish a double-check for accuracy that is preferably completed by the pharmacy team.
7. Develop a standardized process to assess the necessity and methodology for creating separate electronic medication entries for each 505(b)(2) product. Collaborate with the revenue cycle and informatics teams to identify and correctly build 505(b)(2) products in the EHR to ensure that NDCs are associated with the appropriate HCPCS code.
8. Depending on available features and data fields, customize the wholesale distributor portal to help buyers easily identify 505(b)(2) products. Consider incorporating annotations in the purchasing catalog to specify preferred and restricted NDCs for streamlined procurement and compliance.
9. Separate and clearly distinguish the inventory of 505(b)(2) products to prevent confusion with visually similar generics, ensuring accurate selection of product for dispensing.
10. Establish a collaborative workflow between pharmacy, revenue cycle, and other key stakeholders to proactively address 505(b)(2) billing discrepancies during routine charge reviews and reactively resolve claim denials to recover lost revenue. Workflow should be designed to verify payer coverage for 505(b)(2) products and ensure that high-cost 505(b)(2) claim denials are communicated to pharmacy leadership.
11. Develop a strategy for formulary approval of 505(b)(2) products, incorporating considerations for auto-substitution while evaluating the impact on prior authorization requirements. Create an evaluation tool to determine when adding a 505(b)(2) product benefits the organization and when it may not be beneficial. Update policies and procedures accordingly.

# Forward thinking initiatives

## Proactive initiatives

The 505(b)(2) focus group discussed opportunities to mitigate challenges and advocated for key stakeholder engagement to drive systematic changes, aiming to reduce the financial and operations burden of 505(b)(2) products on health systems and dispensing pharmacies. Further efforts may include requesting:

- A different naming convention by FDA so that medications approved via the 505(b)(2) pathway are more easily recognizable (e.g. using a 4-letter suffix similar to biosimilar products). This modification would ease the subsequent workflow challenges associated with drug database information, order entry, purchasing, EHR file build, CDM accuracy, billing, and appropriate therapeutic substitution.
- A centralized database for straightforward identification of the 505(b)(2) approval pathway by NDC and HCPCS code, eliminating the need to reference the NDA approval year or manually search through extensive approval documents.
- The addition of the approval pathway to the physical product label for ease of identifying 505(b)(2) products at the dispensing level.
- The inclusion of the NDA approval pathway in the drug data file, enabling seamless integration with the pharmacy information system.
- The inclusion of the NDA approval pathway on the wholesale distributor portal to enhance informed purchasing.
- Implement a standardized schedule for HCPCS code changes, either by delaying updates until the following quarter or ensuring sufficient advance notice from CMS when immediate changes are necessary, rather than making updates throughout the quarter.
- Notifying providers when the TE rating on a 505(b)(2) product is modified.

## Conclusion

The focus group recognizes that 505(b)(2) products can improve patient care and outcomes by providing different dosage forms, increasing access to medication during drug shortages, and lowering costs. To uphold the highest standards of patient care, pharmacies and providers must be able to accurately identify 505(b)(2) products, understand their financial and operational implications, and implement a comprehensive institutional plan and policy for effective management.

# Subject matter experts

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