



505(b)(2) Drugs: Too Many HCPCS... So Little Time

Bobbi Buell, MBA

WINTER, 2023

650-255-7520

bbuell@onpointoncology.com

BobbiBuell1@yahoo.com

NEWSLETTER: www.onpointoncology.com

Disclaimer

- CPT codes and descriptions only are copyrighted 2023 American Medical Association (AMA). All rights reserved. The AMA assumes no liability for data contained or not contained herein.
- All Medicare information is derived from published rules; however, interpretations may be erroneous and typos may be evidenced. It is mandatory that coding and billing is based on information derived from each patient, provider, practice or clinic.
- This is not legal or payment advice.
- This information is valid for the date of presentation only. This presentation should not be reproduced without the permission of the author and is time sensitive.
- References to the Alchemy Healthcare Solutions webinar of 8/8/23 are with expressed permission of Alchemy Healthcare Solutions LLC..
- This presentation uses brand names to provide examples of certain drug issues. This presentation was not sponsored or underwritten by any drug manufacturer.
- ***Speaker is being compensated for her presentation today by International Oncology Network (“ION”). However, neither ION nor any pharmaceutical company has influenced the content of this presentation nor has ION independently verified the presentation for accuracy.***





Agenda

- Review of FDA approval pathways
- Review of Medicare HCPCS Pathways
- 505(b)(2)s and the HCPCS Storm
- Advantages of 505(b)(2)s
- Best Practices to ensure proper reimbursement



Framework for 505(b)(2) Drugs and HCPCS

FDA Approval Pathways

505(b)1 NDA	Traditional originator drug application, applicant conducts all required safety and efficacy studies. 20 years of patent exclusivity
505(j) ANDA	Traditional generic drug application, applicant must only prove therapeutic equivalence to originator drug. No exclusivity, therapeutically substitutable for originator product.
505(b)2 NDA	Hybrid drug application, applicant may use existing clinical and safety data but offer new or different delivery or formulation that make it not therapeutically equivalent to originator drug. May receive 3 to 7 years of exclusivity depending on attributes of the product and drug application
BLA	Similar to 505(b)1 pathway but for Biologic products

Source: <https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/abbreviated-approval-pathways-drug-product-505b2-or-anda>



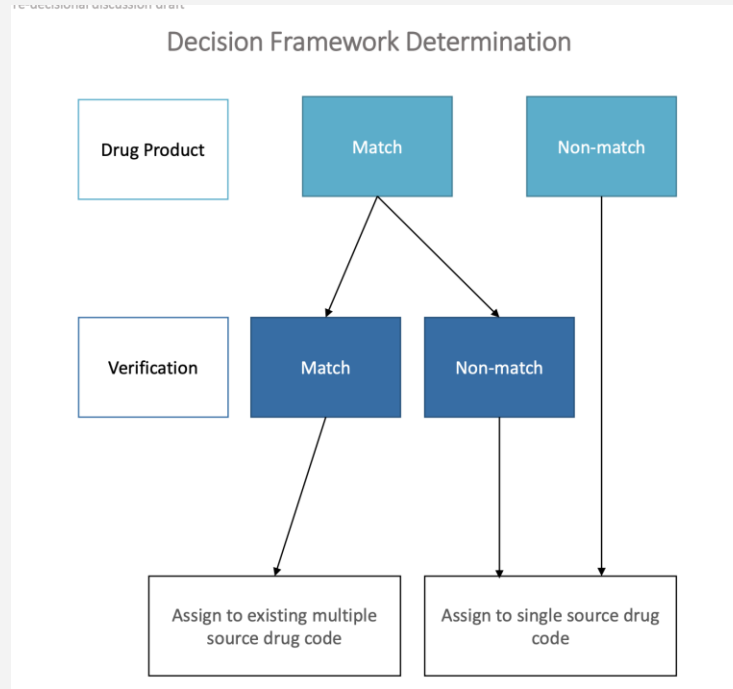
Relevant Medicare Law

- Section 1847A of the Social Security Act provides for separate payments for single source drugs, defined in relevant part as drugs that are:
 - Approved under an NDA, and
 - Not rated as therapeutically equivalent in FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" ("the Orange Book")*

*-Social Security Act, Section 1847A(c)(6)(C),(D)



CMS Decision Tree for 505(b)(2) HCPCS



Source: <https://www.cms.gov/files/document/cy-2022-pfs-proposed-rule-decision-framework.pdf>



Outcome: HCPCS Assignment Changes

- Prior to 2023, a small number of 505(b)(2) products were assigned unique HCPCS codes and ASPs
 - Bendeka/Belrapzo/Bendamustine,
 - Pemfexy/Pemtrexed
- Beginning in January, 2023, the HCPCS team started MMA statutory requirements to reimburse for single source drugs based solely on the drug's ASP resulting in dozens of new HCPCS codes and revised existing codes mostly for 505(b)(2) drugs.

This has created a complex re-ordering of the HCPCS to NDC crosswalks



505(b)(2) Drugs and the HCPCS Storm

What is Going On?

After 2020, the HCPCS climate changed with ongoing drug shortages and increased use of unlisted codes (“NOC” which are unspecified/miscellaneous codes, e.g., J9999 or J3490) due to the swell of provider-administered drug approvals, particularly of 505(b)(2) drugs. According to MMIT*, [60% of approved NDAs](#) were submitted via the 505(b)(2) pathway.

So, the Centers for Medicare & Medicaid Services (CMS) took steps in Fall 2022 to recognize the value of 505(b)(2) value-added medicines **that are not therapeutically equivalent** to their reference products by approving distinct HCPCS codes for them based upon FDA equivalence status. An important change to the approval process was that The Consolidated Appropriations Act of 2022 **now requires CMS to review 505(b)(2) drugs for HCPCS designation within 180 days of launch**. To date (July 2023), 60+ 505(b)(2) products have been assigned a unique code.

*-- <https://www.mmitnetwork.com/thought-leadership/new-hcpcs-codes-for-generics-what-payers-and-manufacturers-should-know-to-ensure-accurate-reimbursement>



What is Going On

- In 2023, CMS has issued approximately 65 new and updated HCPCS codes for 505(b)(2) provider administered drugs.
- CMS has deleted or updated many existing codes to allow for Not Otherwise Specified Codes for originator products and therapeutically equivalent generic competitors.
 - This situation has led to many new HCPCS codes for very similar products, each with their own ASP.
 - Many manufacturers market both a generic and 505(b)(2) branded version of the same drug with different HCPCS codes
- The majority of payers are now requiring NDC codes for medical drug claims and these codes must match the HCPCS for that specific product or claims can get rejected
- Many of these NDCs, particularly for generics, do not appear on the CMS NDC to HCPCS files. Payers and providers must utilize compendia or internal resources to create accurate alignments.



What is Going On

Drug	HCPCS Codes
Pemetrexed	J9294, J9296, J9297, J9304, J9305 , J9314, J9322, J9323
Bendamustine	J9033 , J9034, J9036, J9056, J9058, J9059
Leuprolide:	J1952, J1954, J9217, J9218, J1950
Acetamophen	J0131 , J0134, J0136, J0137
Bortezomib	J9041 , J9046, J9048, J9049, J9051
Gemcitabine	J9196, J9198, J9201
Vancomycin	J3370 , J3371, J3372
Fulvestrant	J9393, J9394, J9395
Cyclophosphamide:	J9070, J9071
Paclitaxel Protein Bound:	J9264 , J9259
Lanreotide	J1930, J1932



Source: Alchemy HealthCare Solutions Webinar 8/8/23



Cancer Drugs With Multiple HCPCS

Compound	HCPCS
Bendamustine	J9033: Injection, bendamustine hcl (treanda), 1 mg
	J9034: Injection, bendamustine hcl (bendeka), 1 mg
	J9036: Injection, bendamustine hydrochloride, (belrapzo/bendamustine), 1 mg
	J9056: Injection, bendamustine hydrochloride (vivimusta), 1 mg
	J9058: Injection, bendamustine hydrochloride (apotex), 1 mg
	J9059: Injection, bendamustine hydrochloride (baxter), 1 mg
Bortezomib	J9041: Injection, bortezomib, 0.1 mg
	J9046: Injection, bortezomib, (dr. reddy's), not therapeutically equivalent to j9041, 0.1 mg
	J9048: Injection, bortezomib (fresenius kabi), not therapeutically equivalent to j9041, 0.1 mg
	J9049: Injection, bortezomib (hospira), not therapeutically equivalent to j9041, 0.1 mg
Fosaprepitant	J1453: Injection, fosaprepitant, 1 mg
	J1456: Injection, fosaprepitant (teva), not therapeutically equivalent to j1453, 1 mg
Fulvestrant	J9393: Injection, fulvestrant (teva) not therapeutically equivalent to J9395, 25 mg
	J9394: Injection, fulvestrant (fresenius kabi) not therapeutically equivalent to j9395, 25 mg
	J9395: Injection, fulvestrant, 25 mg



Cancer Drugs With Multiple HCPCS (Cont'd)

Compound	HCPCS
Leuprolide Depot	J1950: Injection, leuprolide acetate (for depot suspension), per 3.75 mg
	J1951: Injection, leuprolide acetate for depot suspension (fensolvi), 0.25 mg
	J1952: Leuprolide injectable, camcevi, 1 mg
	J1954: Injection, leuprolide acetate for depot suspension (ciplā), 7.5 mg
	J9217: Leuprolide acetate (for depot suspension), 7.5 mg
Pemetrexed	J9294: Injection, pemetrexed (hospira) not therapeutically equivalent to j9305, 10 mg
	J9297: Injection, pemetrexed (sandoz), not therapeutically equivalent to j9305, 10 mg
	J9304: Injection, pemetrexed (pemfexy), 10 mg
	J9305: Injection, pemetrexed, not otherwise specified, 10 mg
	J9314: Injection, pemetrexed (teva) not therapeutically equivalent to j9305, 10 mg
	J9322: Injection, pemetrexed (bluepoint) not therapeutically equivalent to j9305, 10 mg
	J9323: Injection, pemetrexed ditromethamine, 10 mg

A Cancer Care Drug Example

505(b)(2) Report

DRUG NAME	What Are They?	NDC	J-code
Bendamustine	BendaAPO	60505-6228-00	J9058
Bendamustine	BendaBAXTER	60505-6228-00	J9059
Vivamusta	Vivamusta	71225-0120-01	J9056
Belrapso	Belrapso	42367-0521-25, 42367-0520-25	J9036
Bendeka	Bendeka	63459-0348-04	J9034
Treanda	TreandaGen	63459-0391-20, 63459-0391-20	J9033
Bendamustine	BendaGenAPO	60505-6095-00, 60505-6096-00	J9033
Bendamustine	BendaGenMEI	71288-0102-10, 71288-0103-20	J9033
Bendamustine	BendaGenEUGIA	55150-0391-01, 55150-0392-01	J9033
Bendamustine	BendaGenBlueP	68001-0571-41, 68001-0572-41	J9033
Bendamustine	BendaGenACCORD	16729-0251-05, 16729-0250-03	J9033



Bendamustine Case Study

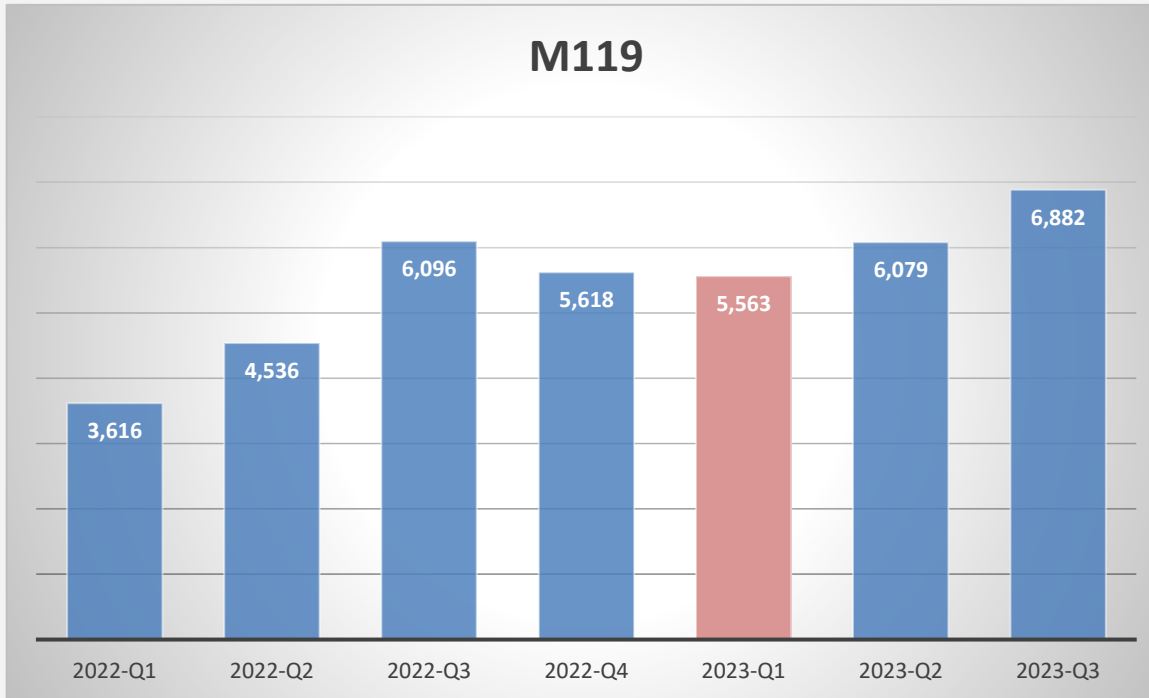
NDC	Manufacturer	Brand Name	NDC First Effective Date	FDA Approval Pathway	CMS ASP X Walk	Compendia 1	Compendia 2	Compendia 3	Compendia 4	BuyandBill.com	HCPCS Code Description
63459-0390-08	TEVA	Treanda	March 2008	505(b)1 NDA	J9033	J9033	J9033	J9033	J9033	J9033	Injection, bendamustine hcl (Treanda), 1 mg
63459-0391-20	TEVA	Treanda	March 2008	505(b)1 NDA	J9033	J9033	J9033	J9033	J9033	J9033	injection, bendamustine hcl (Treanda), 1 mg
63459-0348-04	TEVA	Bendeka	January 2017	505(b)2 NDA	J9034	J9034	J9034	J9034	J9034	J9034	Injection, bendamustine hcl (Bendeka), 1 mg
42367-0520-25	EAGLE	Bendamustine HCl	May 2018	505(b)2 NDA	J9036	NL	J9036	NL	J9036	J9036	Injection, bendamustine hydrochloride, (belrapzo/ bendamustine), 1 mg
42367-0521-25	EAGLE	Belrapzo	July 2019	505(b)2 NDA	J9036	J9036	J9036	J9036	J9036	J9036	Injection, bendamustine hydrochloride, (belrapzo/ bendamustine), 1 mg
16729-0250-03	ACCORD	Bendamustine HCl	December 2022	505(j) ANDA	J9033	J9033	J9033	J9036	J9033	J9033	Injection, bendamustine hcl (Treanda), 1 mg
16729-0251-05	ACCORD	Bendamustine HCl	December 2022	505(j) ANDA	J9033	J9033	J9033	J9036	J9033	J9033	injection, bendamustine hcl (Treanda), 1 mg
60505-6228-00	APOTEX	Bendamustine HCl	Februrary 2023	505(b)2 NDA	NL	J9058	J9058	J9058	J9058	J9058	Injection, bendamustine hydrochloride (Apotex), 1 mg
10019-0079-01	BAXTER	Bendamustine HCl	February 2023	505(b)2 NDA	J9059	J9059	J9059	J9059	J9059	J9059	Inj bendamustine, Baxter 1mg
68001-0571-41	BLUE POINT	Bendamustine HCl	April 2023	505(j) ANDA	NL	J9033	J9036	J9036	N/A	J9033	Injection, bendamustine hcl (Treanda), 1 mg
68001-0572-41	BLUE POINT	Bendamustine HCl	April 2023	505(j) ANDA	NL	J9033	J9036	J9036	N/A	J9033	Injection, bendamustine hcl (Treanda), 1 mg
60505-6095-00	APOTEX	Bendamustine HCl	June 2023	505(j) ANDA	NL	J9033	J9036	J9058	N/A	J9033	injection, bendamustine hcl (Treanda), 1 mg
60505-6096-00	APOTEX	Bendamustine HCl	June 2023	505(j) ANDA	NL	J9033	J9036	J9058	N/A	J9033	Injection, bendamustine hcl (Treanda), 1 mg
55150-0391-01	EUGIA	Bendamustine HCl	June 2023	505(j) ANDA	NL	J9033	J9036	J9036	N/A	J9033	Injection, bendamustine hcl (Treanda), 1 mg
55150-0392-01	EUGIA	Bendamustine HCl	June 2023	505(j) ANDA	NL	J9033	J9036	J9036	N/A	J9033	Injection, bendamustine hcl (Treanda), 1 mg
71288-0102-10	MEITHEAL	Bendamustine HCl	June 2023	505(j) ANDA	NL	J9033	J9033	J9036	N/A	J9033	Injection, bendamustine hcl (Treanda), 1 mg
71288-0103-20	MEITHEAL	Bendamustine HCl	June 2023	505(j) ANDA	NL	J9033	J9033	J9036	N/A	J9033	Injection, bendamustine hcl (Treanda), 1 mg
71225-0120-01	SLAYBACK	Vivimusta	July 2023	505(b)2 NDA	J9056	J9056	J9056	J9056	J9056	J9056	Injection, bendamustine hydrochloride (Vivimusta), 1 mg



Disadvantages/Advantages of 505(b)(2)s

Denial Code 16, Remark M119—Wrong or Missing NDCs

Source: onPoint Proprietary Database (3.0 Claims/EOBs 2023)
Adjudicated Claims



Disadvantages of 505(b)(2)s

- **Keeping up with the quarterly load of codes is hard on providers.** CMS issues codes each quarter; plus, manufacturers gain additional 505(b)(2)s approvals on an ongoing basis. Providers must constantly change their computerized charge documents to reflect these changes. The last thing stretched offices and clinics need is more administrative tasks.
<https://www.mmitnetwork.com/thought-leadership/new-hcpcs-codes-for-generics-what-payers-and-manufacturers-should-know-to-ensure-accurate-reimbursement/>



Disadvantages of 505(b)(2)s

- **505(b)(2) drug prices are a challenge for practices as they can fluctuate from quarter to quarter.** Additionally, drug costs change as do discounts and rebates from distributors. The right drug for a practice or clinic may be a daunting task as the best price for 505(b)(2) may change again the very next quarter, while the Average Sales Price for Medicare reimbursement may also increase or decrease. Also, the best option in terms of allowed amount may not be available from your distributor.
- **505(b)(2)s with unique HCPCS are also new for non-Medicare payers. Payers adopt new HCPCS in varying time frames.** The large payers, like United, CVS/Aetna, and CIGNA, usually adopt new codes quickly. Smaller payers and Medicaid do not—another issue for HCPs. But, even if the HCPCS is adopted, with all 505(b)(2)s, generics, biosimilars and branded drugs HCPCS, it is dubious that all payers have correctly adopted all changes for 65 codes since the beginning of 2023. This may be causing adjudication delays and unnecessary claim denials.



Advantages of 505(b)(2)

- There are less NOC (Unspecified) HCPCS Codes and better, faster billing with unique HCPCS. According to our most recent survey, 20%* of practices/clinics will not bill a drug until it receives its own HCPCS. The reason is each NOC code must be manually reviewed by insurers. This causes delays and denials of drug claims and frustration for HCPs.
- These products, particularly those 505(b)(2)s that are branded (e.g., Pemfexy, Camcevi, Fensolvi), have programs to assist patients, which generics do not. Due to the quick de-escalation of prices and reimbursements with generics, many manufacturers abandon their Patient Assistance, Commercial Co-pay cards, and Foundation programs for patient access. Many of the 505(b)(2) drugs are branded and maintain these programs which are valued by M.D. offices, patients, and advocacy organizations.

*--onPoint Oncology *E-Reimbursement News* Annual Survey, 2023 (N = 125)



Advantages of 505(b)(2)

- Practices can explore which product fits their facility's chair traffic. Some 505(b)(2)s have the same active ingredient and approved for the same indications but may have differing infusion times and routes.
 - For example, Bendeka and Belrapso are two 505(b)(2) bendamustines that have the same active ingredients and indications. Belrapso has a 30- or 60-minute infusion time, while Bendeka's is 10 minutes.
 - Busy practices might prefer shorter infusion times as they can serve more patients in a single day, even with lower drug administration payments. Conversely, smaller practices might prefer to keep their infusion suite full and may select drugs with longer infusion times to fill their chars each day. 505(b)(2) offer flexibility to meet every facility's needs.
- Some 505(b)(2)s can help participating practices minimize risk in the Enhancing Oncology Model ("EOM") because some drugs in particular indications are classified as 'novel' therapies. While there is no penalty for NOT using Novel Therapies in the EOM, the Novel Therapy Adjustment ("NTA") is an upward adjustment for each of the approved in the EOM 7 tumor types to each 6-month episode. The adjustment is to account for the use of innovative drugs in certain indications without a negative impact on the targeted benchmarks by tumor for that period. A CMMI NTA example is enclosed.
 - There are 505(b)(2) oncologics on the [EOM Novel Therapies List](#) such as pemetrexed, bendamustine, and bortezomib. One might not expect these therapies to be novel, but they are!

Best Practices: Pharma and Practices

Best Practices: 505 (b)(2) Pharma

- **Keep it simple! Ensure that a one-page cheat sheet is distributed to customers.** This sheet should include applicable ICD-10-CM codes, NDC codes, HCPCS plus HCPCS units per vial, administration CPT codes, and links to the most current CMS Average Sales Price information for product verification.
- **Update non-Medicare payers, particularly smaller commercial and Medicaid plans regarding the appropriate HCPCS and NDC crosswalks for your product.** It is very frustrating for HCPs when the payer does not recognize a code or has the wrong NDCs cross-walked to a code or pays at wrong price. Providing accurate information to payers will assist practices and clinics in generating clean claims and distinguish one 505(b)(2) from others.



Best Practices: Pharma

- **Provide the right tools for updated pricing and coding information.** Most providers do not have subscriptions to the pricing compendia. A pricing website, *BuyandBill.com* (<https://buyandbill.com>) is updated every quarter and offers free look up that has pricing by NDC and HCPCS code. Manufacturers can also use this tool to ensure that the very latest and correct information regarding their product(s) is in the public domain.

Disclaimer: onPoint Oncology does not have a financial relationship with Alchemy Health, parent company to Buyandbill.com.



Best Practices: Community Oncology

- **Keep up to date**: Make sure you look at the Quarterly HCPCS and update charge documents for the drugs that you use. CMS and onPoint publish new codes every quarter. So, you have no excuse! <https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update>
- **Communicate**: NDCs are not on drug packaging. Ensure that your pharmacy (or nursing) knows that the NDCs are quite important with these drugs and the brand or generic drugmaker name must be specified for billing. Remember some manufacturers have generics and 505s!



Best Practices: Community Oncology

- **Compare Allowables for all drug with the same active ingredient each quarter by NDC (not HCPCS).** Remember all products may not be available to you.
- **Check all of your CO-16, M119 denials for 505(b)(2)s to make sure you have not confused products or NDCs.** If you don't check, you are bound to make the same mistake again.



Thank you for taking care of cancer patients..



References

- <https://www.cms.gov/files/document/cy-2022-pfs-proposed-rule-decision-framework.pdf>
- <https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update>
- <https://www.mmitnetwork.com/thought-leadership/new-hcpcs-codes-for-generics-what-payers-and-manufacturers-should-know-to-ensure-accurate-reimbursement/>
- [https://premierconsulting.com/resources/what-is-505b2/#:~:text=The%20provisions%20of%20505\(b,developed%20by%20the%20NDA%20applicant.](https://premierconsulting.com/resources/what-is-505b2/#:~:text=The%20provisions%20of%20505(b,developed%20by%20the%20NDA%20applicant.)
- <https://www.pharmacytimes.com/view/the-enhancing-oncology-model-promotes-novel-therapies-may-reduce-cost-of-care>

