

**Coverage of any drug intervention discussed in the plans prior authorization guideline is subject to the limitations and exclusions outlined in the member's benefit certificate or policy and to applicable state and/or federal laws.**

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- Commercial (Small & Large Group)       ASO       Exchange/ACA  
 Medicare Advantage (MAPD)
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**New-to-Market Medical Pharmacy Products**

**MB2211**

**Covered Service:** Yes

**Prior Authorization Required:** N/A

**Additional Information:** None

**Medicare Policy:** Prior authorization is not required for Medicare Cost products (Dean Care Gold) and Medicare Supplement (Select) when this drug is provided by participating providers. Prior authorization is required if a member has Medicare primary and the plan secondary coverage. This policy is not applicable to our Medicare Replacement products.

**Wisconsin Medicaid Policy** Coverage of prescription drug benefits is administered by the Wisconsin Medicaid program. Coverage of medical drug benefits is administered by the Wisconsin Medicaid fee-for-service program. Medical drugs not paid on a fee-for-service basis by the Wisconsin Medicaid program are covered by the plan with no PA required.

**Important Information – Please Read Before Using This Policy**

These services may or may not be covered by all Dean Health Plan (DHP) plans. Please refer to the member's plan document for specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. Members may contact Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this coverage policy may call the Plan Call Center toll-free at 1-800-279-1301.

Coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

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### **Coverage Policy**

The Plan will not cover new-to-market professionally administered medical pharmacy products until they are reviewed and approved for coverage by the Plan for commercial, individual and family business members. Prior authorization will apply to new-to-market professionally administered medical pharmacy products immediately upon approval by the FDA for members in Medicare Advantage. Any new-to-market biosimilar medications will follow the strategy in place for the reference product.

For this purpose, professionally administered medical pharmacy products are those (1) with routes of administration including, but not limited to, intravenous infusion or injection, intrathecal infusion or injection, intramuscular injection, or intraocular injection; and (2) that are administered under the member's medical benefit. New-to-market means up to six months from the date of final approval by the U.S. Food and Drug Administration (FDA). A reference product is a large, complex biological product approved by FDA based on a full complement of safety and effectiveness data. A biosimilar product is compared to and evaluated against a reference product to ensure that the product is highly similar and has no clinically meaningful differences.

The Plan will conduct a clinical review for each new-to-market medical pharmacy product in a timeframe not to exceed six months after final FDA approval. The Plan will review clinical data and patient safety information and provide a coverage determination for each product reviewed.

Please refer to <https://www.deancare.com/document-repository?keyword=&audience=Provider&category=DrugPolicies> and <https://www.mrxgateway.com/policyDisplay/99/dean-health-clinical-guidelines> to view the current list of Coverage Policies and Utilization Management Policies that result from the Plan's clinical review process. Please refer to '[Medicare Part B Utilization Management in Absence of NCD or LCD](#)' to view the policy and review criteria for Medicare prior authorizations.

Note: The Plan does not cover services that are not medically necessary and/or are investigative. Individual cases may be considered by the medical director.

### **Prior Authorization**

Prior authorization is not applicable for commercial, individual, and family business. Prior authorization is applicable according to CMS guidelines for members in Medicare Advantage. Claims for this service are subject to retrospective review and denial of coverage.

### **Coding Considerations**

Professionally administered medical pharmacy products which have been recently approved by the FDA typically do not have a permanent HCPCS code assigned to them. Claims for unlisted and non-specific drug codes require submission of the 11-digit National

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Drug Code (NDC) in the correct format and location on the claim form. The Unlisted Drug Code List identifies all codes that require the submission of an NDC. If the NDC is not submitted, the claim will not be processed and will be returned for correction. Claims for these products are submitted using a temporary code and the product's national drug code (NDC) added to one of the following miscellaneous drug codes:

**HCPCS Codes:**

- J3490 - Unclassified drug - injection
- J3590 - Unclassified biologic
- J7199 - Hemophilia clotting factor, not otherwise classified
- J7599 - Immunosuppressive drug, not otherwise classified
- J9999 - Not otherwise classified, antineoplastic drug
- A9699 - Radiopharmaceutical, therapeutic, not otherwise classified

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