Medica (formerly WellFirst Health)

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

☒ **Commercial (Small & Large Group)** ☒ **ASO** ☒ **Exchange/ACA**
☒ **Medicare Advantage (MAPD)**

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.mrxgateway.com/policyDisplay/99 to view the current list of Coverage Policies and Utilization Management Policies that result from the Plan's clinical review process.

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. 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 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:

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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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