Medica Coverage Policy

Policy Name:	**New-to-Market Medical Pharmacy Products**
Effective Date:	**10/16/2019**

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica 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. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

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

Coverage Policy

Medica will not cover new-to-market professionally administered medical pharmacy products until they are reviewed and approved for coverage by Medica for commercial, individual and family business and Minnesota Health Care Programs (MHCP) members. Prior authorization will apply to new-to-market professionally administered medical pharmacy products immediately upon approval by the FDA for members in DUAL Solution (Minnesota Senior Health Options, or MSHO) and Advantage Solution (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.

Medica 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. Medica will review clinical data and patient safety information and provide a coverage determination for each product reviewed.

Please refer to https://www.medica.com/providers/policies-and-guidelines/drug-management-policies to view the current list of Coverage Policies and Utilization Management Policies that result from Medica's clinical review process.

Note: Medica does not cover services that are not medically necessary and/or 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 these products are submitted using a temporary code or 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

Original Effective Date:	6/1/2017
Re-Review Date(s):	1/1/2018
	10/16/2019