CLINICAL MEDICAL POLICY	
Policy Name:	Pharmacogenomic Testing for Warfarin Response (NCD 90.1)
Policy Number:	MP-044-MC-PA
Responsible Department(s):	Medical Management
Provider Notice/Issue Date:	10/01/2023; 11/01/2022; 10/15/2021; 10/19/2020; 11/18/2019; 11/15/2018; 06/01/2018
Effective Date:	11/01/2023; 12/01/2022; 11/15/2021; 11/16/2020; 11/18/2019; 11/15/2018; 06/01/2018
Next Annual Review:	09/2024
Revision Date:	09/20/2023; 09/21/2022; 09/15/2021; 09/16/2020; 09/18/2019; 09/19/2018
Products:	Pennsylvania Medicare Assured
Application:	All participating and nonparticipating practitioners and facilities unless contractually precluded
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Policy History

Date	Activity
11/01/2023	Provider Effective date
09/20/2023	QI/UM Committee review
09/20/2023	Annual Review: No changes to clinical criteria. Updated CMS hyperlink. Updated 'Reference Sources' section.
12/01/2022	Provider Effective date
09/21/2022	QI/UM Committee review
09/21/2022	Annual Review: No changes to clinical criteria. Updated CMS hyperlinks, added LCA & related LCD hyperlinks. Corrected CPT code 31355 code description. Updated 'Reference Sources' section.
11/15/2021	Provider effective date
09/15/2021	QI/UM Committee review
09/15/2021	Annual Review: Added place of service statement. Ensured all links were active and working. Reviewed CMS, no new updates to NCD or coding.
11/16/2020	Provider Effective Date
09/16/2020	QI/UM Committee Review
09/16/2020	Annual Review: Edited policy into new format by removing the references to attachments, removing the policy criteria (Benefit category, Item/Service Description, Indications and Limitations of Coverage). Per the new format, Links to CMS, the NCD,

	and CMS Transmittals were added. Moved references section under Links, added Transmittal 1889 reference. Revised Operational Guidelines; clarified CPT code requirements in Coding Requirements by removing 81227 & 81355 and leaving G 9143 as covered; added QO modifier requirement; added ICD-10 diagnosis codes Z00.6 & Z7.01 as eligible conditions.
11/18/2019	Provider effective date
09/18/2019	Annual Review: Policy statement updated to include the coverage of CED; operational guidelines were updated to include the CED coverage; format changes
09/18/2019	QI/UM Committee Review
03/01/2018	Initial policy developed

Disclaimer

Highmark Wholecare℠ medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

Policy Statement

Highmark Wholecare℠ does not provide coverage for genetic testing for warfarin therapy initiation under the medical-surgical benefits of the Company's Medicare products. Highmark Wholecare℠ may only provide coverage for pharmacogenomic testing of CYP2C9 or VKORC1 alleles to predict warfarin responsiveness in alignment with the CMS Coverage with Evidence Development (CED).

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

Procedures

1. Please review the specific National Coverage Determination (NCD), Local Coverage Determination (LCD), and/or Local Coverage Article (LCA) information, as well as other CMS sources, using the links below.

2. Post-payment Audit Statement
   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Wholecare℠ at any time pursuant to the terms of your provider agreement.

3. Place of Service
   Please refer to the NCD, LCD, LCA, and/or CMS guidelines for the proper place of service for pharmacogenomic testing for warfarin response.

Coverage Determination and Links

Highmark Wholecare℠ follows the coverage determinations made by CMS as outlined in either the NCD or the state-specific LCD/LCA.

CMS Link

- CMS Website

NCD/LCD Links:

- NCD: Pharmacogenomic Testing for Warfarin Response (90.1)
- There are no current LCDs related to this topic.
- Related LCD: Pharmacogenomics Testing (L39063)

Related Article Link:

- Billing and Coding: Pharmacogenomics Testing (A58801)

Transmittals:

- Transmittal 111: Pharmacogenomic Testing for Warfarin Response
- Pub 100-04 Medicare Claims Processing (Transmittal 1889)

Reference Sources

Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) Pharmacogenomic Testing for Warfarin Response (90.1). Effective date August 3, 2009. Implementation date April 5, 2010. Accessed on August 28, 2023.

Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD) Pharmacogenomics Testing (L39063). Original Effective date December 12, 2021. Accessed on August 28, 2023.

Centers for Medicare and Medicaid Services (CMS). Local Coverage Article (LCA) Billing and Coding: Pharmacogenomics Testing (A58801). Original Effective date December 12, 2021. Revision Effective date February 7, 2022. Accessed on August 28, 2023.

Centers for Medicare and Medicaid Services (CMS). Manual System Pub 100-03 Medicare National Coverage Determinations, Transmittal 111. December 18, 2009. Accessed on August 28, 2023.

Centers for Medicare and Medicaid Services (CMS). Manual System Pub 100-04 Medicare Claims Processing, Transmittal 1889. January 8, 2010. Accessed on August 28, 2023.

Coding Requirements

Procedure Code

HCPCS Code	Description
G9143	Warfarin responsiveness testing by genetic technique using any method, any number of specimen(s)

Noncovered Procedure Codes

CPT Code	Description
81227	CYP2C9 (cytochrome P450, family 2, subfamily C, polypeptide 9) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *5, *6)
81355	VKORC1 (vitamin K epoxide reductase complex, subunit 1) (eg, warfarin metabolism), gene analysis, common variant(s) (eg, -1639G>A, c.173+1000C>T)

Note: HCPCS modifier 'QO' is required when the service is provided in a clinical research study that is in an approved clinical research study.

Diagnosis Codes

ICD-10 Code	Description
Z00.6	Encounter for examination for normal comparison and control in clinical research program
Z79.01	Long-term (current) use of anticoagulants

Reimbursement

Participating facilities will be reimbursed per their Highmark Wholecare℠ contract.