

MEDICAL POLICY

POLICY TITLE	GENETIC TESTING FOR STATIN-INDUCED MYOPATHY
POLICY NUMBER	MP 2.361

CLINICAL BENEFIT	<input type="checkbox"/> MINIMIZE SAFETY RISK OR CONCERN. <input checked="" type="checkbox"/> MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. <input type="checkbox"/> ASSURE APPROPRIATE LEVEL OF CARE. <input type="checkbox"/> ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. <input type="checkbox"/> ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. <input type="checkbox"/> ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	6/1/2024

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I. POLICY

Genetic testing for the presence of variants in the *SLCO1B1* gene to identify members at risk of statin-induced myopathy is considered **not medically necessary**.

Genetic testing for the presence of variants in the *SLCO1B1* is considered **investigational** in all other situations. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: <https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies>

III. DESCRIPTION/BACKGROUND

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Statins

HMG-CoA reductase inhibitors, or statin drugs, are the primary pharmacologic treatment for hypercholesterolemia worldwide. In the United States, an estimated 38 million people took statins in 2008. The use of statins is associated with an approximately 30% reduction in cardiovascular events across a wide variety of populations. A variety of socioeconomic disparities in cardiovascular outcomes and implementation of risk-reducing measures, including use of statins and other agents for managing hypercholesterolemia, have been identified. Women with coronary artery disease are less likely to be receiving a statin than men, and those taking statins are less likely to have therapy intensified and to achieve lipid control

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compared to men taking statins. Black individuals at high risk of atherosclerotic cardiovascular disease are significantly less likely to be prescribed statins compared to similar White individuals, and rates of lipid control are lower among Black and non-White Hispanic individuals taking statins compared to White individuals taking statins. These observations are mediated in part through disparities in social determinants of health, such as income, insurance, and immigration status.

Commercially Available *SLCO1B* Molecular Diagnostic Tests

Several commercial and academic labs offer genetic testing for statin-induced myopathy (*SLCO1B1*) variants, including Boston Heart Diagnostics and ARUP Laboratories. Other labs offer panel tests for drug metabolism that include the *SLCO1B1* gene.

Regulatory Status

Clinical laboratories may develop and validate tests in-house and market them as a laboratory service; laboratory-developed tests must meet the general regulatory standards of the Clinical Laboratory Improvement Amendments. The Boston Heart Statin Induced Myopathy (*SLCO1B1*) Genotype test and ARUP Laboratories Statin Sensitivity *SLCO1B1* are available under the auspices of the Clinical Laboratory Improvement Amendments. Laboratories that offer laboratory-developed tests must be licensed by the Clinical Laboratory Improvement Amendments for high-complexity testing. To date, the Food and Drug Administration has chosen not to require any regulatory review of this test.

IV. RATIONALE

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Summary of Evidence

For individuals who are taking statin drugs who receive genetic testing for *SLCO1B1* variants, the evidence includes a systematic review and two randomized controlled trials (RCTs). Relevant outcomes are symptoms, quality of life, morbid events, and treatment-related morbidity. Direct evidence for clinical utility in this setting would come from studies demonstrating that using the *SLCO1B1* genotype to inform statin therapy (statin dose or choice of a specific drug) has positive outcomes in terms of lower rates of myopathy with adequate lipid control and tolerability of alternative treatments. The systematic review findings suggested that certain alleles carry less risk of statin-induced myopathy compared with others. Two randomized controlled trials were identified that evaluated adherence to medication and/or lipid control in patients whose physicians were informed of the *SLCO1B1* haplotype at the beginning or at the end of the study. No significant benefits were identified in adherence to medications or in pain related to myopathy with knowledge of the *SLCO1B1* haplotype status. There was a short-term (3-month) decrease in low-density lipoprotein (LDL) in the active treatment group in one trial, but knowledge of *SLCO1B1* status did not provide benefit in LDL lowering in the other trial after 12 months. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

V. DEFINITIONS

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N/A

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VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross' medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Not medically necessary; therefore, not covered:

Procedure Codes							
81328							

IX. REFERENCES

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X. POLICY HISTORY

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MP 2.361	5/7/2018 New policy. BCBSA adopted. Genetic testing for statin-induced myopathy is considered not medically necessary.
	3/25/2019 Consensus review. No changes to policy statements. References updated.
	3/12/2020 Consensus review. No changes to policy statements. References reviewed and updated. FEP variation updated.

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	5/10/2021 Consensus review. Policy statement unchanged. Background, Rationale and References updated.
	11/27/2022 Consensus review. Policy statement unchanged. References, background, rationale reviewed and updated. FEP variation updated. Policy statement change from patients to members, no change to intent.
	12/20/2023 Consensus review. Policy statement unchanged. References updated.

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