This protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

RELATED PROTOCOL
None

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DESCRIPTION
HMG-CoA reductase inhibitors, or statins, which are widely used to treat hypercholesterolemia, can cause muscle-related adverse events. Serious myopathy (i.e., myositis, rhabdomyolysis) can also occur and may be associated with variants in the SLCO1B1 gene. Commercially available tests for the presence of SLCO1B1 variants are marketed for use in predicting the risk of myopathy for patients taking statins.

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. 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 ad-
herence 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.

POLICY

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

BACKGROUND

STATINS

HMG-CoA reductase inhibitors, or statin drugs, are the primary pharmacologic treatment for hypercholesterolemia worldwide. In the U. S., 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.

COMMERCIALY 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; for example, ApolloGen.

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 U.S. Food and Drug Administration has chosen not to require any regulatory review of this test.

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.