

Genetic Testing for Statin-Induced Myopathy

Last Review Date: November 9, 2018

Number: MG.MM.LA.23C3

Medical Guideline Disclaimer

Property of EmblemHealth. All rights reserved. The treating physician or primary care provider must submit to EmblemHealth the clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request for prior authorization. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary. If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication. EmblemHealth Services Company LLC, ("EmblemHealth") has adopted the herein policy in providing management, administrative and other services to HIP Health Plan of New York, HIP Insurance Company of New York, Group Health Incorporated and GHI HMO Select, related to health benefit plans offered by these entities. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Statin-induced myopathy is a side effect that occurs in susceptible individuals taking statin for the treatment of hypercholesterolemia and coronary artery disease. Inherited variations on the SLCO1B1 gene appear to increase the risk of statin-induced myopathy and reduce effectiveness of statin therapy. Statin-induced myopathy is categorized into statin-induced myalgia, statin-induced myositis and statin-induced rhabdomyolysis.

Guideline

Genetic testing of variants in the SLCO1B1 gene to identify individuals at increased risk of statin-induced myopathy is considered investigational and not medically necessary.

Applicable Procedure Codes

81400	Molecular pathology procedure, Level 1 (eg, identification of single germline variant [eg, SNP] by techniques such as restriction enzyme digestion or melt curve analysis) (Revision eff. 01/01/2018)
--------------	---

References

1. Brunham LR, Lansberg PJ, Zhang L et al. Differential effect of the rs4149056 variant in SLCO1B1 on myopathy associated with simvastatin and atorvastatin. *Pharmacogenomics J* 2012; 12(3):233-7.
<http://www.nature.com/tpj/journal/v12/n3/full/tpj201092a.html>. Accessed November 9, 2018.
2. Drobny M, Pullmann R, Odalos I, et al. Incidence of skeletal muscle disorders after statins' treatment: consequences in clinical and EMG picture. *Neuro Endocrinol Lett*. 2014; 35(2):123-128.
3. Santos, P., Soares, R., Nascimento, R. M., Machado-Coelho, G., Mill, J. G., Krieger, J. E., et al. (2011). SLCO1B1 rs4149056 polymorphism associated with statin-induced myopathy is differently distributed according to ethnicity in the Brazilian general population: Amerindians as a high risk ethnic group. *BMC Medical Genetics*, 12:136. (Level 2 Evidence)
4. SEARCH Collaborative Group, Link E, Parish S et al. SLCO1B1 variants and statin-induced myopathy--a genomewide study. *N Engl J Med* 2008; 359(8):789-99.
<http://www.nejm.org/doi/full/10.1056/NEJMoa0801936#t=articleBackground>. Accessed November 9, 2018.

5. Stewart A. SLCO1B1 polymorphisms and statin-induced myopathy. *PLoS Curr.* 2013; 5. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3871416/?report=printable>. Accessed November 9, 2018.
6. Stone NJ, Robinson J, Lichtenstein AH, et al. 2013 ACC/AHA guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *Circulation.* 2014; 129(25 Suppl 2):S1-S45. <https://www.ahajournals.org/doi/abs/10.1161/01.cir.0000437738.63853.7a>. Accessed November 9, 2018.
7. Voora, D., Shah, S. H., Spasojevic, I., Ali, S., Reed, C. R., Salisbury, B. A., et al. (2009). The SLCO1B1*5 genetic variant is associated with statin-induced side effects. *Journal of the American College of Cardiology*, 54 (17), 1609-1616. (Level 2 Evidence - Industry sponsored)
8. Wilke RA, Ramsey LB, Johnson SG et al. The clinical pharmacogenomics implementation consortium: CPIC guideline for SLCO1B1 and simvastatin-induced myopathy. *Clin Pharmacol Ther* 2012; 92(1):112-7. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3384438/>. Accessed November 9, 2018.
9. Wilke, R. A., Ramsey, L. B., Johnson, S. G., Maxwell, W. D., McLeod, H. L., Voora, D., et al. (2012). The Clinical Pharmacogenomics Implementation Consortium: CPIC guideline for SLCO1B1 and simvastatin-induced myopathy. *Clinical Pharmacology & Therapeutics*, 92 (1), 112-117.
10. Woolley T, Canoniero M, Conroy W, et al. Institute for Clinical Systems Improvement (ICSI). Lipid Management in Adults. Updated Feb. 2017. https://www.icsi.org/_asset/qz5ydg/LipidMgmt-Interactive1111.pdf. Accessed November 9, 2018.
11. Specialty matched clinical peer review.