

To: All McLaren Health Plan Providers

From: McLaren Health Plan (MHP) Medical Management Department

Date: January 2021

Re: Genetic Testing Pre-authorization requirements

As you know, MHP promotes the traditional primary care relationship between physicians and their patients. PCPs are generally responsible to issue referrals for care outside of the PCP office setting. We do recognize that there are certain situations and circumstances in which the specialist provider would be more appropriate to request pre-authorization for services. Therefore, referrals and requests for pre-authorization are accepted from both the PCP and Specialist Providers.

Of special interest and as a reminder, MHP requires pre-authorization for all genetic testing including prenatal genetic testing.

When considering the medical necessity of genetic testing, MHP Medical Management utilizes a variety of criteria such as, Hayes and Apollo Medical Necessity Criteria as well as "II Questions to Ask When Making Genetic Testing Coverage Decisions" (Allingham-Hawkins, Wieselquist, Spock, 2015).*

It is the responsibility of the <u>ordering practitioner</u> to provide the following information with any request for pre-authorization of genetic testing:

- I. Is this test appropriate for this patient?
- 2. Is the technical and clinical performance of the genetic test supported by peer-reviewed published research?
- 3. Does a definitive diagnosis remain uncertain despite a comprehensive workup that includes a detailed medical history, physical examination, pedigree analysis, genetic counseling, and completion of conventional diagnostic studies?
- 4. Will the test result impact or alter the medical management of the patient?
- 5. What are the limitations of the test?
- 6. Are there any major ethical, legal or safety issues of concern with the test?
- 7. Has the genetic test been cleared or approved by the U.S. Food and Drug Administration or will it be performed in a Clinical Laboratory Improvement Amendment-certified laboratory?
- 8. Is this a targeted test or a multi-gene panel?
- 9. Has a pathogenic variant been identified in an affected family member?
- 10. Is this the first time this test is being performed on this patient?
- 11. Has the genetic test been ordered by a medical professional such as a medical geneticist, developmental-behavioral pediatrician, condition-specific subspecialist, or neonatologist in the NICU, who has training in genetics and will ensure that face-to-face genetic counseling by appropriately trained professional(s) will accompany testing?

If you would like a copy of any medical necessity criteria, or if you have any questions regarding genetic testing and the pre-authorization requirement, please call Medical Management at (888) 327-0671.

McLaren Health Plan thanks you for the quality care you deliver!

*Allingham-Hawkins, D. J., Wieselquist, L., & Spock, L. (2015). IT Questions to ask when making genetic testing coverage decisions. Lansdale, PA: Hayes Inc.