MetroPlus Health Plan

Policy and Procedure

Title: Whole Genome Sequencing	Division: Medical Management Department: Utilization Management
Approval Date: 6/8/18	LOB: Medicaid, Medicare, HIV SNP, CHP, MetroPlus Gold, Goldcare I&II, Market Plus, Essential, HARP, MLTC
Effective Date: 6/8/18	Policy Number: UM-MP247
Review Date: 8/2/19	Cross Reference Number:
Retired Date:	Page 1 of 4

Policy Description

Whole genome sequencing (WGS) (CPT codes 81425-81427) is considered experimental, investigational, and unproven for any indication.

No specific documentation of how the information will be used to modify member's treatment. MetroPlus considers 'Whole Genome Sequencing' experimental and investigational and therefore it is denied as not medically necessary.

A genome is the genetic code of all the hereditary information contained in an individual's DNA. Whole genome sequencing, also called genomic sequencing, is a testing strategy to analyze both the coding and non-coding portions of the genome.

Whole Genome Sequencing

1. For use of whole genome sequencing (WGS) to identify or confirm the genetic etiology of a known or unknown disorder in clinically affected neonatal and pediatric patients. This Rating reflects an assessment of articles relevant only to clinical utility and for which a low-quality body of evidence was observed, the limitations of this report, and the emerging use of this technology. The Rating weighs the benefit from identification of the underlying genetic cause(s) of the disease(s), the impact on patient clinical management, and the ability to alter the management of family members resulting from WGS of the proband, and balances this with the current limitations of WGS and the potential harms and ethical concerns resulting from WGS of pediatric patients.
    a. **Hayes Rating: C** – Potential but unproven benefit. Some published evidence suggests that safety and impact on health outcomes are at least comparable to standard treatment/testing. However, substantial uncertainty remains about safety and/or impact on health outcomes because of poor-quality studies, sparse data, conflicting study results, and/or other concerns.

2. For use of WGS for newborn screening. This Rating reflects the lack of studies that demonstrate the clinical utility of WGS for this indication.

a. **Hayes Rating: D2** – Insufficient evidence. There is insufficient published evidence to assess the safety and/or impact on health outcomes or patient management.

References

1. Hayes, Inc. Genetic Testing Evaluation (GTE) Report. Whole Genome Sequencing (WGS) in Neonatal and Pediatric Patients. http://www.hayesinc.com. Published September 22, 2016. Updated June 6, 2018. Accessed May 23, 2019.

2. Hayes, Inc. Genetic Testing Evaluation (GTE) Report. Whole exome sequencing for cancer indications. http://www.hayesinc.com. Published July 22, 2013. Updated July 1, 2014. Accessed May 23, 2019.

3. Hayes, Inc. Genetic Testing Evaluation (GTE) Report. Whole exome sequencing for noncancer indications. http://www.hayesinc.com. Published August 13, 2013. Updated August 12, 2014. Accessed May 23, 2019.

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REVISION LOG:

REVISIONS	DATE
Creation date	6/8/18
Annual Review	8/2/19

Approved:	Date:	Approved:	Date:
	8/14/19		8/16/19
Sosler Bruce, MD Clinical Medical Director		Sanjiv Shah, MD Chief Medical Officer	

Medical Guideline Disclaimer:

Property of Metro Plus Health Plan. All rights reserved. The treating physician or primary care provider must submit MetroPlus Health Plan clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, Metroplus Health Plan will not be able to properly review the request for prior authorization. The clinical review criteria expressed in this policy reflects how MetroPlus Health Plan determines whether certain services or supplies are medically necessary. MetroPlus Health Plan 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). MetroPlus Health Plan 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 MetroPlus Health Plan, as some programs exclude coverage for services or supplies that MetroPlus Health Plan considers medically necessary. If there is a discrepancy between this guidelines 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 website links are accurate at time of publication.