**Policy Name:** Whole Genome Sequencing  
**Effective Date:** 8/19/2019

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**Important Information – Please Read Before Using This Policy**

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage.

Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

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**Coverage Policy**
Whole genome sequencing is investigative and unproven and therefore **NOT COVERED**. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

**Description**
Deoxyribonucleic acid (DNA) is a chemical compound that contains the genetic instructions needed to develop and direct the activities of every organism. A genome is an organism’s complete set of DNA, including all of its genes. Changes in the genes that make up the genome, such that the sequence differs from what is found in most people, are called mutations or variants. Mutations can be beneficial, neutral or harmful. Harmful mutations can increase an individual’s risk of developing certain diseases.

Major advances in technology have made it possible to do large-scale sequencing, including whole genome sequencing (WGS). High-throughput next generation sequencing (NGS), also known as massively parallel sequencing, permits rapid sequencing of large numbers of segments of DNA at a time, as opposed to initial approaches that involved sequencing one strand of DNA at a time. Whole genome sequencing refers to determining the DNA sequence of the entire genome.

Considerable interest exists in using WGS in the clinical setting for the evaluation and management of many conditions, including cancer, adult neurologic disorders, neurodevelopmental disorders in children, and a number of other undiagnosed genetic disorders. However, while WGS has the advantages of speed and efficiency, many limitations exist, including technical and implementation challenges, the implications of variants of unknown significance and incidental findings, and legal, ethical and societal issues.

**FDA Approval**
On November 19, 2013, the FDA announced the first regulatory clearance of the Illumina MiSeq Dx, a sophisticated high-throughput DNA sequencing device. Since then new sequencing platforms and instruments have been developed and approved specifically for high-throughput sequencing of whole exomes and whole genomes. WES tests are offered commercially through various manufacturers and many medical centers as a clinical service, however, no FDA-approved tests for WGS are available at this time. Genetic tests are regulated under the Clinical
Laboratory Improvement Amendments (CLIA) Act of 1988. Premarket approval from the FDA is not required as long as the assay is performed in a laboratory facility that observes CLIA regulations and the test is not marketed for general distribution.

**Prior Authorization**
Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement.

**Coding Considerations**
Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

**CPT Codes**
- 81425 - Genome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis
- 81426 - Genome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis, each comparator genome (eg, parents, siblings) (List separately in addition to code for primary procedure)
- 81427 - Genome (eg, unexplained constitutional or heritable disorder or syndrome); re-evaluation of previously obtained genome sequence (eg, updated knowledge or unrelated condition/syndrome)

Original Effective Date: 1/1/2014

Re-Review Date(s): 6/15/2016
6/26/2019
3/18/2020 – administrative update; format