

State of Minnesota

H. F. No. **3330**

2.1 Subd. 3. Coverage criteria. Coverage may be based on the following medical necessity  
2.2 criteria:

2.3 (1) the enrollee has symptoms that suggest a broad differential diagnosis that would  
2.4 require an evaluation by multiple genetic tests if rWGS testing is not performed;

2.5 (2) timely identification of a molecular diagnosis is necessary in order to guide clinical  
2.6 decision making, and the rWGS testing may aid in guiding the treatment or management  
2.7 of the enrollee's condition; and

2.8 (3) the enrollee's complex or acute illness of unknown etiology includes at least one of  
2.9 the following conditions:

2.10 (i) congenital anomalies involving at least two organ systems, or complex or multiple  
2.11 congenital anomalies in one organ system;

2.12 (ii) specific organ malformations that are highly suggestive of a genetic etiology;

2.13 (iii) abnormal laboratory tests or abnormal chemistry profiles suggesting the presence  
2.14 of a genetic disease, complex metabolic disorder, or inborn error of metabolism;

2.15 (iv) refractory or severe hypoglycemia or hyperglycemia;

2.16 (v) abnormal response to therapy related to an underlying medical condition affecting  
2.17 vital organs or bodily systems;

2.18 (vi) severe muscle weakness, rigidity, or spasticity;

2.19 (vii) refractory seizures;

2.20 (viii) a high-risk stratification on evaluation for a brief resolved unexplained event with  
2.21 any of the following features:

2.22 (A) a recurrent event without respiratory infection;

2.23 (B) a recurrent seizure-like event; or

2.24 (C) a recurrent cardiopulmonary resuscitation;

2.25 (ix) abnormal cardiac diagnostic testing results that are suggestive of possible  
2.26 channelopathies, arrhythmias, cardiomyopathies, myocarditis, or structural heart disease;

2.27 (x) abnormal diagnostic imaging studies that are suggestive of underlying genetic  
2.28 condition;

2.29 (xi) abnormal physiologic function studies that are suggestive of an underlying genetic  
2.30 etiology; or

3.1 (xii) family genetic history related to the patient's condition.

3.2 Subd. 4. **Cost sharing.** Coverage provided in this section is subject to the enrollee's  
3.3 health plan cost-sharing requirements, including any deductibles, co-payments, or coinsurance  
3.4 requirements that apply to diagnostic testing services.

3.5 Subd. 5. **Reimbursement.** If the enrollee's health plan uses a capitated or bundled  
3.6 payment arrangement to reimburse a provider for services provided in an inpatient setting,  
3.7 reimbursement for services covered under this section must be paid separately and in addition  
3.8 to any reimbursement otherwise payable to the provider under the capitated or bundled  
3.9 payment arrangement, unless the health carrier and the provider have negotiated an increased  
3.10 capitated or bundled payment rate that includes the services covered under this section.

3.11 Subd. 6. **Genetic data.** Genetic data generated as a result of performing rWGS and  
3.12 covered under this section: (1) must be used for the primary purpose of assisting the ordering  
3.13 provider and treating care team to diagnose and treat the patient; (2) is protected health  
3.14 information as set forth under the Health Information Portability and Accountability Act  
3.15 (HIPAA), the Health Information Technology for Economic and Clinical Health Act, and  
3.16 any promulgated regulations, including but not limited to the HIPAA Privacy Rule under  
3.17 Code of Federal Regulations, title 45, parts 160 and 164, subparts A and E; and (3) is a  
3.18 protected health record under the Minnesota Health Records Act under section 144.291.

3.19 **EFFECTIVE DATE.** This section is effective January 1, 2024, and applies to a health  
3.20 plan offered, issued, or sold on or after that date.