Hennepin Health
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Rare Disease and Unexplained Developmental Delay

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Policy statement

Hennepin Health evaluates requests for services related to rare diseases and unexplained developmental delay based on the criteria outlined below. A rare disease does not include infectious diseases for which widely available diagnostic and treatment protocols exist, and which are commonly managed in primary care settings, even if the condition affects fewer than 200,000 individuals in the United States.

Coverage decisions remain subject to the member's health plan benefits. Hennepin Health is not required to cover medications, procedures, treatments, or laboratory/clinical testing not included in the member's benefit plan. Coverage must not be denied solely because the service is provided, referred, or ordered by an out-of-network provider. Prior authorization requirements for out-of-network providers must be the same as those applied to in-network providers.

I. Initial approval – out-of-network requests

1. Routing process
    - Any out of network specialty service request received by UM Administrative staff in the outpatient queue must be routed to the UM RN team.
2. Rare disease verification
    - The UM RN will verify whether the diagnosis is listed on the NIH Rare Disease database (https://rarediseases.info.nih.gov).
    - If the diagnosis is confirmed as a rare disease, the request will be approved for **6 months**.
3. Cases not meeting rare disease criteria
    - If the diagnosis is *not* listed and does not clearly meet criteria for a rare disease, the case is routed to a Medical Director.

- If there is suspicion that the condition may represent a rare disease, the request must also be reviewed by a Medical Director.

4. Denied claims or referrals
    - Any claim or referral for out-of-network specialty care being denied by Provider Services must be routed to the UM team.
    - The UM RN will verify whether the associated diagnosis appears on the Rare Disease list.
    - All denials are reviewed by a Medical Director.
    - If the Medical Director determines that the member has a rare disease or condition, the request for out-of-network coverage will be approved.

II. Renewal process

- Renewal requests must be evaluated using the same criteria listed above.
- If criteria are met, the authorization may be renewed for an additional **6 months**.

III. Unexplained developmental delay – approval criteria

A referral or claim for **out-of-network specialty services** must be approved when all of the following criteria are met:

1. The member has received **two or more clinical consultations** from a primary care or specialty provider specific to the presenting complaint.
2. Documentation exists in the medical record indicating a developmental delay demonstrated by at least one of the following:
    - standardized developmental assessment
    - developmental regression
    - failure to thrive
    - progressive multisystemic involvement
3. Laboratory or clinical testing has **not** produced a definitive diagnosis **or** produced conflicting results.

Further resources for review are available through the NIH Rare Disease information line at **1-888-205-2311**.