Department: Utilization Management	Policy and Procedure No: MCD-OH-CLI-H1084	
Policy and Procedure Title: Diabetes Mellitus (Transient Neonatal Diabetes)ABCC8, HYMAI, KCNJ11, PLAGL1, and ZFP57 Genes Medical Necessity		abetes)ABCC8,
Process Cycle: Annually	Responsible Departments: Clinical	
Approved By: Dr. Mark Rastetter	Effective Date: 2/1/2023	Revised:

POLICY AND PROCEDURE:

Policy:

Humana Healthy Horizons[™] of Ohio will use established criteria guidelines to make medical necessity decisions on case-by-case basis, based on the information provided on the member's health status.

Procedure:

For ABCC8, HYMAI, KCNJ11, PLAGL1, and ZFP57 Genes services, Humana Healthy Horizons in Ohio uses MCG® criteria.

MCG® criteria is nationally recognized and URAC (Utilization Review Accreditation Commission) certified. It is proprietary and cannot be publicly published and/or distributed. On an individual member or provider basis, the specific medical necessity criteria will be made available upon request.

Members may request a copy of the medical necessity criteria by calling member services at 877-856-5702 (TTY:711), Monday-Friday, from 7 a.m. to 8 p.m.

Providers may submit a request for medical necessity request by calling 877-856-5707 (TTY:711), Monday – Friday, from 7 a.m. to 8 p.m. EST or emailing the request to <u>OHMCDUM@humana.com</u>.

Related codes include, but are not limited to:

CPT [®] Code(s)	Description
81479	Unlisted molecular pathology procedure
CPT® Category III Code(s)	Description
	N/A
HCPCS Code(s)	Description
	N/A

1) The Plan covers all benefits and services required in OAC chapter 5160 in the amount, duration, and scope for the same services furnished to members under the fee-for-service (FFS) Medicaid.

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- 2) When applying coverage policies and medical necessity criteria, the Plan will consider individual member needs and an assessment of the local delivery system.
- 3) The Plan uses the following hierarchy of guidelines to review for medical necessity:
 - a) Federal or state regulation, including medical criteria published in the Ohio Administrative Code, Chapter 5160.
 - b) Nationally accepted evidence based clinical guidelines: MCG (formerly Milliman Care Guidelines), American Society of Addiction Medicine (ASAM) Level of Care Adolescent Guidelines and American Society of Addiction Medicine (ASAM) Patient Placement Criteria (ASAM Admission Guidelines)
 - c) Humana Healthy Horizons in Ohio clinical policies
 - d) In the case of no guidance from above, additional information that the clinical reviewer will consider, when available, includes:
 - i. Clinical practice guidelines and reports from peer reviewed medical literature, from which a higher level of evidence and study quality is more strongly considered in determinations;
 - ii. Professional standards of safety and effectiveness recognized in the US for diagnosis, care, or treatment;
 - iii. Medical association publications
 - iv. Government-funded or independent entities that assess and report on clinical care
 - v. decisions and technology such as Agency for Healthcare Research and Quality (AHRQ), Hayes Technology Assessment, Up-To-Date, Cochrane Reviews, National Institute for Health and Care Excellence (NICE), etc.;
 - vi. Published expert opinions;
 - vii. Opinion of health professionals in the area of specialty involved;
 - viii. Opinion of attending provider
 - e) Dental: DentaQuest coverage guidelines and policies

Dental Coverage - Humana Healthy Horizons in Ohio | Humana

f) Vision: EyeMed coverage guidelines and policies
<u>Vision Care - Humana Healthy Horizons - Ohio Medicaid | Humana</u>

Only practitioners with the appropriate clinical expertise can make the decision to deny or reduce the amount, duration or scope of the services being requested.

Humana Healthy Horizons[™] in Ohio requires prior authorization on all "Miscellaneous", "Unlisted", "Not Otherwise Specified" codes. Medical necessity documentation and rationale must be submitted with the prior authorization request. The medical director adheres to the above process to align criteria based on the information provided on the member's health status.

Humana | Healthy Horizons_™ in Ohio

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RESOURCES:

- Ohio Administrative Code 5160-1-01 Medicaid medical necessity: definitions and principles. Retrieved October 28, 2022, from <u>https://codes.ohio.gov/ohio-administrative-code/5160</u>
- MCG® <u>https://www.mcg.com/care-guidelines/care-guidelines/</u>

CONTRACT LANGUAGE:

5. Coverage Requirements

a. Medical Necessity Criteria

- i. Pursuant to OAC rule 5160-26-03, the MCO's coverage requirements and decisions must be based on the coverage and medical necessity criteria published in OAC Chapter 5160 and practice guidelines as specified in OAC rule 5160-26-05.1.
- ii. The MCO must have objective, written criteria based on sound clinical evidence to make medical necessity and utilization decisions. The MCO must involve appropriate providers in the development, adoption, and review of medical necessity criteria. The MCO's written criteria must meet NCQA standards and must specify procedures for appropriately applying the criteria.
- iii. The MCO must use ODM-developed medical necessity criteria where it exists. In the absence of ODM-developed medical necessity criteria, the MCO must use clinically-accepted, evidence-informed medical necessity criteria (e.g., InterQual®, MCG®, and ASAM) as approved by ODM.
- iv. In the absence of ODM-developed medical necessity criteria or ODM-approved, clinically-accepted, evidence-informed medical necessity criteria, the MCO's adaptation or development of medical necessity criteria must be based upon evaluated, peer reviewed medical literature published in the United States.
 - 1. Peer reviewed medical literature must include investigations that have been reproduced by non-affiliated authoritative sources.
 - 2. The literature must also include positive endorsements by national medical bodies or panels regarding scientific efficacy and rationale that is based upon well-designed research and endorsements by national medical bodies or panels regarding scientific efficacy and rationale.
- v. When applying coverage policies and medical necessity criteria, the MCO must consider individual member needs and an assessment of the local delivery system.

DEFINITIONS:

Department: Utilization Management	Policy and Procedure No: MCD-OH-CLI-H1084
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Adverse Benefit Determination – As defined in OAC rule 5160-26-08 4, a Managed Care	

Adverse Benefit Determination – As defined in OAC rule 5160-26-08.4, a Managed Care Organization's (MCO's):

- a. Denial or limited authorization of a requested service, including determinations based on the type or level of service, requirements for medical necessity' appropriateness, setting, or effectiveness of a covered benefit;
- b. Reduction, suspension, or termination of services prior to the member receiving the services previously authorized by the MCO;
- c. Denial, in whole or part, of payment for a service (a denial, in whole or in part, of a payment for a service solely because the claim does not meet the definition of a "clean claim" is not an adverse benefit determination);
- d. Failure to provide services in a timely manner as specified in OAC rule 5160-26-03.1;
- e. Failure to act within the resolution timeframes specified in this rule; or
- f. Denial of a member's request to dispute a financial liability, including cost sharing, co-payments, premiums, deductibles, coinsurance, and other member financial liabilities, if applicable.

American Society of Addiction Medicine (ASAM) – a professional medical society representing over 7,000 physicians, clinicians, and associated professionals in the field of addiction medicine. ASAM produces a comprehensive set of standards for placement, continued stay, transfer or discharge of patients with addition and co-occurring conditions used by clinical staff to determine whether to refer a service request for physician review based upon the clinical information submitted by the requestor.

MCG® – Formerly known as Milliman Care Guidelines, are nationally recognized guidelines used by clinical staff to determine whether to refer a service request for physician review based upon the clinical information submitted by the requestor.

Medically Necessary or Medical Necessity – Has the same meaning as OAC rule 5160-1-01:

- a. Medical necessity for individuals covered by early and periodic screening, diagnosis, and treatment (EPSDT) is defined as procedures, items, or services that prevent, diagnose, evaluate, correct, ameliorate, or treat an adverse health condition such as an illness, injury, disease or its symptoms, emotional or behavioral dysfunction, intellectual deficit, cognitive impairment, or developmental disability.
- b. Medical necessity for individuals not covered by EPSDT is defined as procedures, items, or services that prevent, diagnose, evaluate, or treat an adverse health condition such as an illness, injury, disease or its symptoms, emotional or behavioral dysfunction, intellectual deficit, cognitive impairment, or developmental disability, and without which the person can be expected to suffer prolonged, increased, or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort.
- c. Conditions of medical necessity are met if all the following apply:
 - i. It meets generally accepted standards of medical practice;
 - ii. It clinically appropriate in its type, frequency, extent, duration, and delivery setting;
 - iii. It is appropriate to the adverse health condition for which it is provided and is expected to produce the desired outcome;

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iv. It is the lowest cost altern medical problem:	ative that effectively addresse	es and treats the

- v. Provides unique, essential, and appropriate information if it is used for diagnostic purposes; and
- vi. It is not provided primarily for the economic benefit of the provider nor for the convenience of the provider or anyone else other than the recipient.
- d. The fact that a physician, dentist, or other licensed practitioner renders, prescribes, orders, certifies, recommends, approves, or submits a claim for a procedure, item, or service does not, in and of itself, make the procedure, item, or service medically necessary and does not guarantee payment for it.
- e. The definition and conditions of medical necessity articulated in this rule apply throughout the entire Medicaid program. More specific criteria regarding the conditions of medical necessity for particular categories of service may be set forth within ODM coverage policies or rules.

VERSION CONTROL

Version Review Approval History				
Department:	Purpose of Review	Reviewed and Approved By:	Date:	Additional Comments:
Clinical	Policy Development	Dr. Mark Rastetter	12/11/2022	Comments.

DISCLAIMER:

Humana follows all federal and state laws and regulations. Where more than one state is impacted by an issue, to allow for consistency, Humana will follow the most stringent requirement.

This document is intended as a guideline. Situations may arise in which professional judgment may necessitate actions that differ from the guideline. Circumstances that justify the variation from the guideline should be noted and submitted to the appropriate business area for review and documentation. This (policy/procedure) is subject to change or termination by Humana at any time. Humana has full and final discretionary authority for its interpretation and application. This (policy/procedure) supersedes all other policies, requirements, procedures or information conflicting with it. If viewing a printed version of this document, please refer to the electronic copy maintained by CMU to ensure no modifications have been made.

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NON-COMPLIANCE:

Failing to comply with any part of Humana's policies, procedures, and guidelines may result in disciplinary actions up to and including termination of employment, services or relationship with Humana. In addition, state and/or federal agencies may take action in accordance with applicable laws, rules and regulations.

Any unlawful act involving Humana systems or information may result in Humana turning over all evidence of unlawful activity to appropriate authorities. Information on handling sanctions related to non-compliance with this policy may be found in the Expectations for Performance, and Critical Offenses policies, both of which may be found in the Associate Support Center via Humana's secure intranet of Hi! (Workday & Apps/Associate Support Center).

Diabetes Mellitus (Transient Neonatal Diabetes) - ABCC8, HYMAI, KCNJ11, PLAGL1, and ZFP57 Genes

MCG Health

Ambulatory Care 26th Edition

ACG: A-0825 (AC) Link to Codes

- Clinical Indications for Procedure
- Alternatives to Procedure
- Evidence Summary
 - Background
 - Criteria
- References
- Footnotes
- Codes

Clinical Indications for Procedure

- ABCC8, HYMAI, KCNJ11, PLAGL1, and ZFP57 gene testing may be indicated when ALL of the following are present(1)(2)(3):
 - o Clinical findings suggestive of transient neonatal diabetes, as indicated by ALL of the

following:

- Age of onset of hyperglycemia younger than 6 weeks
- Intrauterine growth retardation in term infant
- Nonketotic hyperglycemia (plasma glucose concentration at least 150 to 200 mg/dL (8.32 to 11.10 mmol/L))
- Need for gene testing, as indicated by **1 or more** of the following:
 - ABCC8 and KCNJ11 gene sequencing, when DNA methylation analysis of PLAGL1 and HYMAI genes (ie, 6q24 region) is normal
 - PLAGL1 and HYMAI genes (ie, 6q24 region) deletion and duplication analysis, when DNA methylation analysis of PLAGL1 and HYMAI genes (ie, 6q24 region) is abnormal^[A]
 - ZFP57 gene sequencing, when ALL of the following are present:
 - DNA methylation analysis of PLAGL1 and HYMAI genes (ie, 6q24 region) is abnormal.

- Deletion and duplication analysis of PLAGL1 and HYMAI genes (ie, 6q24 region) is normal.
- Uniparental disomy testing of chromosome 6 is normal.
- o Genetic counseling has been performed, as indicated by ALL of the

following(13)(14)(15):

- Counseling is provided by healthcare professional with education and training in genetic issues relevant to the genetic tests under consideration.^[B]
- Counselor is free of commercial bias and discloses all (potential and real) financial and intellectual conflicts of interest.
- Process involves individual or family and is comprised of ALL of the following(40)(41):
 - Calculation and communication of genetic risks after obtaining 3-generation family history(42)(43)
 - Discussion of natural history of condition in question, including role of heredity
 - Discussion of possible impacts of testing (eg, psychological, social, limitations of nondiscrimination statutes)
 - Discussion of possible test outcomes (ie, positive, negative, variant of uncertain significance)
 - Explanation of potential benefits, risks, and limitations of testing
 - Explanation of purpose of evaluation (eg, to confirm, diagnose, or exclude genetic condition)
 - Identification of medical management issues, including available prevention, surveillance, and treatment options and their implications
 - Obtaining informed consent for genetic test(44)(45)

Alternatives to Procedure

- Alternatives include(2):
 - Molecular testing, including **1** or more of the following(1)(3)(11):
 - Methylation testing of HYMAI and PLAGL1 genes (ie, 6q24 region)^[A]
 - Uniparental disomy testing of chromosome 6 or of 6q24 region(2)
 - Monitoring for relapse of diabetes after puberty(12)

Evidence Summary Background

Diabetes mellitus may be attributed to monogenic inheritance in approximately 1% of all cases.(4) **(EG** 2) Monogenic forms of diabetes include maturity-onset diabetes of the young, permanent neonatal diabetes, and transient neonatal diabetes(2); polygenic forms include type 1 diabetes mellitus and type 2 diabetes mellitus.(2)(5) **(EG 2)**

Transient neonatal diabetes most commonly results from overexpression of imprinted genes at chromosome 6q24 (PLAGL1 and HYMAI); PLAGL1 and HYMAI overexpression occurs via paternal duplication of PLAGL1 and HYMAI genes, hypomethylation of the maternal PLAGL1 and HYMAI imprinting control region, paternal uniparental disomy of chromosome 6, or mutations of ZFP57.(3)(6)(7) (EG 2) Mutations of ABCC8 and KCNJ11 may be causative in up to 25% of cases.(8) (EG 2) Fewer than 1% of cases are attributed to mutations in other genes (eg, INS, HNF1B, SLC2A2).(1)(9) (EG 2) An international cohort study of 1020 patients with diabetes diagnosed before 6 months of age, including 219 patients with transient neonatal diabetes, found several gene mutations that were associated with transient neonatal diabetes; in 210 patients, overexpression of paternal alleles at the 6q24 region or mutations in ABCC8 or KCNJ11 genes were detected.(10) (EG 2) No clinical features reliably differentiate permanent from transient neonatal diabetes.(3) (EG 2) A consensus specialty society guideline and a review article indicate that neonatal diabetes may be differentiated from type 1 diabetes mellitus by detectable C-peptide and absence of islet autoantibodies; however, the latter may not be reliable, as maternal antibodies may be present in the neonate for up to 6 months.(1)(2) (EG 2) Genetic counseling recommendations will vary with the underlying molecular defect, including the particular mechanism causing PLAGL1 and HYMAI gene (ie, 6q24 region) overexpression.(2) (EG 2)

Criteria

For transient neonatal diabetes, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** Diagnosis often requires several different molecular techniques in a sequential strategy. Methylation analysis of PLAGL1 and HYMAI genes (ie, 6q24 region) is often the first test performed. If methylation testing is abnormal, and secondary tests for uniparental disomy and for duplications are negative, then sequencing the ZFP57 gene for biallelic mutations is appropriate.(1)(3)(9) **(EG 2)** However, if no methylation abnormality is detected, sequencing the ABCC8 and KCNJ11 genes is appropriate.(3)(9)(10) **(EG 2)** Identifying PLAGL1 and HYMAI (ie, 6q24 region) overexpression caused by hypomethylation or biallelic ZFP57 gene mutations may confirm the diagnosis of transient neonatal diabetes, help determine prognosis, and suggest the need to monitor for relapse in adolescence or young adulthood. KCNJ11 and ABCC8 mutations are typically characterized by onset in the late neonatal period (ie, older than 3 weeks of age) and less extreme intrauterine growth retardation.(6)(9)(11) **(EG 2)** Most cases of transient neonatal diabetes present by 6 weeks of age and may last until 18 months of age; the reported median age for resolution is 12 weeks. Patients with a past medical history of transient neonatal diabetes may relapse in adolescence or young adulthood.(2)(3)(12) **(EG 2)**

For genetic counseling, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** Genetic counseling is a specialized skill set that can be performed by clinicians who receive appropriate training and have core competencies. Various professional societies outside of genetic medicine, including primary care and non-genetic medicine subspecialty societies, have created core competencies for physicians and other healthcare professionals relevant to their area of practice to enable successful incorporation of genetic medicine into practice.(16)(17)(18)(19)(20) (EG 2) The limited number of studies that compare the outcomes of counseling from genetics specialists vs non-genetics specialists report contradictory findings.(21)(22)(23) (EG 2) Several studies demonstrate deficiencies in knowledge or counseling provided by non-genetics

specialists.(24)(25)(26)(27)(28) (**EG 2**) Genetic counseling should be provided prior to the testing by a clinician who has received the education and training to gather a complete family history, perform detailed pretest counseling, obtain fully informed consent, and order the appropriate test. The ordering clinician should be capable of properly interpreting the results and should perform post-test counseling.(29)(30)(31)(32)(33) (**EG 2**) The choice of a genetics counselor may depend on factors such as patient needs, provider knowledge, resource availability, sufficiency of visit time, and test complexity.(18)(34)(35)(36)(37) (**EG 2**) Certain types of genetic tests have sufficient complexity that obtaining informed consent, preparing the patient for potentially uninformative results, and interpreting the returned results require a trained geneticist or genetics counselor (eg, multigene panels, whole exome sequencing).(18)(38)(39) (**EG 2**)

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Footnotes

[A] In approximately 70% of cases, transient neonatal diabetes is attributed to the overexpression of genes in the 6q24 region of chromosome 6, which contains the HYMAI and PLAGL1 genes. The maternal HYMAI and PLAGL1

genes (ie, 6q24 region) are normally silenced by methylation, while the unmethylated paternal HYMAI and PLAGL1 genes (ie, 6q24 region) are expressed.(3)(6) [A in Context Link 1, 2]

[B] Various professional societies, including those for primary care and subspecialties, have created core competencies for physicians and other healthcare professionals in their area of practice to enable successful incorporation of genetic medicine into practice.(16)(17)(18)(19) [B in Context Link 1]

Codes

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