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DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. 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 (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage — each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

According to the Centers for Disease Control and Prevention (1 CDC, 2022), 1 in 6 children (17%) between the ages of 3 and 17 in the United States have a developmental disability or a developmental delay. These can begin during the developmental period and typically last through one's lifetime however, some occur due to injury, infection, or other factors. This includes parental health and behavior during pregnancy (e.g., smoking, drinking) as well as complications during birth or early in the child's life. Maternal exposure to environmental toxins is also a factor. (1 CDC, 2022).

The highest rates of developmental disabilities were among children in their teens, male, had public health insurance, had low birthweight, those living in poverty and those in rural areas had the highest rates of developmental disabilities. Increases are attributed to improved identification of developmental disabilities and updated diagnostic criteria. The most common developmental disabilities include (Zablotsky et al., 2019):

- Attention-Deficit/Hyperactivity Disorder (ADHD) (9.5%)
- Learning Disability (7.9%)
- Other Developmental Delay (4.1%)
- Autism Spectrum Disorder (ASD) (2.5%)
- Stuttering or Stammering, past 12 months (2.1%)
- Intellectual Disability (1.2%)
- Seizures, past 12 months (0.8%)
- Moderate/Profound Hearing Loss (0.6%)
- Cerebral Palsy (0.3%)
- Blindness (0.2%)

The identification and diagnosis of developmental disabilities has increased over the last three decades in large part due to awareness, surveillance, screening, increased prenatal risk factors (e.g., older parental age, multiple births), and increased survival of children born preterm with congenital anomalies and genetic disorders. A large focus has been on ASD and ADHD as well as increased positive outcomes for all developmental disabilities due to early intervention. (Aites & Schonwald, 2022). Assessments are performed using standardized, valid, and reliable instruments that are age-appropriate for the child's level of functioning. In addition, the child's language, culture, communication, socioeconomic status, and disability profile should also be considered. Appropriate referrals should be given for specialists and further testing, if warranted, to determine the child's educational and individual support needs including early intervention services. (Pivalizza, 2022).

Early Intervention

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Of those who have a developmental delay, 20% receive early intervention before age 3. While early intervention can improve the cognitive and academic performance of high-risk children, less than 50% of clinicians are using standardized screening tools in practice – this is largely due to time constraints and a lack of training. Common screening tools include the Ages and Stages Questionnaire (ASQ), the Parents' Evaluation of Developmental Status, and the Child Development Inventory; standardized developmental assessments using ASQ are mandatory at 9, 18, and 24 or 30 months. (Balasundaram & Avulakunta, 2023).

Early intervention is the process of providing services, education, and support to young children who are deemed to have an established condition. This includes those who are evaluated and deemed to have:

- a diagnosed physical or mental condition (with a high probability of resulting in a developmental delay),
- · an existing delay or a child who is at-risk of developing a delay, or
- a special need that may affect their development or impede their education.

Early Intervention Programs are typically a first option for children who qualify and are up to age 3 years. Each state has special programs available for education and related services. The purpose of early intervention is to lessen the effects of the disability or delay. Services are designed to identify and meet a child's needs in five developmental areas: physical, cognitive, communication, social or emotional, and adaptive. An early intervention program is available within each State (refer to State-specific criteria).

The Individuals with Disabilities Education Act was passed to ensure availability of free, public education to eligible children with disabilities, including special education and related services. Over 7.5 million infants, toddlers, children, and youth with disabilities currently receive services. Children and youth ages 3 through 21 are covered under Part B. Infants and toddlers, birth through age 2 years, are covered under Part A. Grants are also provided to support special education and related services as well as early intervention services. Educational and nonprofit organizations may also be eligible for grants to support research, technical assistance and development, personnel preparation and development, and parent-training and -information centers. (U.S. Dept. of Education, 2017).

Children who demonstrate a possible delay or disability based on initial screening assessments should undergo a more comprehensive developmental testing evaluation. Services are designed to identify and meet a child's needs in five developmental areas: physical, cognitive, communication, social or emotional, and adaptive. An early intervention program is available within each State (refer to State-specific criteria). The results of testing services are intended to inform needs for additional treatment planning or services.

COVERAGE POLICY

NOTE: State specific criteria for developmental testing supersedes information in this policy.

Testing related to developmental delay is covered when the following criteria are met:

- 1. Child is age 18 years or younger*; AND
- 2. Developmental screening established the possibility of disability and further assessment is required; AND
- 3. Testing is used to:
 - a. Help clarify diagnostically complex and ambiguous cases; OR
 - b. Further evaluate a specific cognitive domain; OR
 - c. Determine educational placements and to tailor educational plans; OR
 - d. Determine pre-post comparisons after intervention (e.g., medication) or injury (e.g., head trauma).

AND

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- 4. Testing is performed by a developmental pediatrician, child psychologist, or other trained provider; **AND**
- 5. Testing is performed using a current, clinically sound validated testing tool that is used in its entirety (utilizing subsets of a tool is not accepted and the request will not be covered); **AND**
- A separate identifiable report is produced, and the medical record is documented to include that the screening tool is scored.
 - * Refer to Appendix for State specific information and age requirements.

Additional Testing

Additional testing may be required following an initial, detailed diagnostic evaluation for developmental testing. Further testing **is covered** when the following criteria are met:

- Member has been prescribed various treatment but has not progressed, symptoms persist, and ALL the following are met:
 - Requested number of hours or units for testing does not exceed the reasonable time necessary to address
 the clinical questions with the identified measures; AND
 - Testing techniques are:
 - o Validated for the proposed diagnostic question or treatment plan; AND
 - o Do not represent redundant measurements of the same domain; AND
 - o Validated for the age and population of the member.

Limitations and Exclusions

The following limitations and exclusions include:

 Preventive counseling for risk factor reduction for developmental delay, including the administration of health risk assessment tools.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

Meurer et al. (2022) analyzed the preventive screening assessment results of more than 30,000 children in the age groups 8 to 12 months, 13 to 24 months, and 25 to 36 months. This included the review of the electronic health record (EHR) from 25 clinics and 150 providers in Wisconsin between April 2017 to April 2019. Within 25 months, all three age groups saw an increase in screening rates from 60% to >95%. Lower screening rates were found among those enrolled in Medicaid, Black children, and children who live in lower income zip codes. Significant differences were found among responses to the ASQ (3rd ed.) with respect to gender, race/ethnicity, insurance, and income categories. Despite age group or insurance, no significant differences were found in continuing current therapy and referral rates. In addition, quality improvement interventions were a focus. Clinics that were part of the review emphasized the designation of clinic champions, staff education regarding the screening process and responsibilities, how to use

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Commented [RB1]: This would only be applied to Ohio Medicaid members after they have exhausted their initial 20 hours/encounters of testing/services and requesting to continue the testing/services.

Molina Clinical Policy

Developmental Testing: Policy No. 432

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standardized tools, engaging plan-do-study-act cycles, posting EHR prompts, offering financial incentives, and using control charts to monitor screening rates. The study authors note that the ASQ had some limitations including completion prior to the visit. Providers noted that it would be more efficient to complete the tool directly into the EHR. This could be completed by the patient's parent or caregiver prior to a visit via an online website. Providers noted the length of the ASQ as another limitation.

Lipkin et al. (12020) analyzed data from the American Academy of Pediatrics Periodic Survey data from 2002, 2009, and 2016. The survey focused on Provider knowledge, attitudes, and practices about screening and referrals for developmental issues. Reported use of standardized developmental screening tools increased from 21% in 2002 to 63% in 2016. Referrals are crucial to evaluating the etiology and co-occurring conditions however only 46% of Providers who responded to the survey noted referring a patient for speech and language delays, hearing loss, and neurogenetic conditions. Use of centralized electronic referral systems, patient navigators, tracking systems, and early intervention (EI) partnerships have led to improved referral rates to EI programs and services. However, survey respondents listed inconsistent quality of EI programs as a barrier to referrals (24% in 2002 and 30% in 2016). The most-reported barrier to referral in 2016 was the lack of program feedback (38%) – this highlights the need for improved communication between pediatricians and local EI specialists. The authors note the importance of continued enhancement of referral systems, improving EI programs, and improved methods for tracking child outcomes.

Lipkin et al. (² 2020) discuss a universal system for surveillance and screening of developmental conditions which include autism, deafness / hard-of-hearing, intellectual and motor disabilities, and behavioral conditions. Surveillance data are collected at health supervision visits, in addition to the administration of standardized screening tests at the 9-, 18-, and 30-month visits. Developmental surveillance includes communication with early childhood professionals in childcare, preschools, Head Start, and other programs – this includes home visitation and parenting, especially regarding developmental screening. The authors outline a 15-step algorithm for screening patients without identified risks for developmental problems at a health supervision visit.

- 1. Step 1: Patient Without Identified Risks or Developmental Problems Arrives for Health Supervision Visit
- 2. Step 2: Is This a 9-, 18-, 24-, or 30-Month Visit?
- 3. Step 3: Administer Screening Test
- 4. Step 4: Perform Physical Exam and Routine Developmental Surveillance (Including Risk Factor Assessment)
- 5. Step 5: Does the Screening Suggest a Motor Concern?
- 6. Step 6: Is the Screening Result Concerning?
- 7. Step 7: Perform Motor Disorder Evaluation
- 8. Step 8: Perform Complete Medical Evaluation
- 9. Step 9: Perform or Refer for Developmental Evaluation, Refer to Early Intervention or Early Childhood Education
- 10. Step 10: Unaddressed Concern from Surveillance?
- 11. Step 11: Identify Concern in Record System
- 12. Step 12: Set Early Return Flag
- 13. Step 13: Perform Remainder of Health Supervision Visit
- 14. Steps 14 and 15: Developmental Diagnosis Established? and Initiate Chronic Condition Management

Zuckerman et al. (2014) performed a narrative review to examine racial, ethnic, and language disparities in early childhood developmental and behavioral assessments. The authors also studied the screening, referral, and evaluation process for early childhood developmental and behavioral conditions as well as racial/ethnic and language disparities. For example, African American and Latino children are diagnosed less often with ASD and usually at an older age and more severe symptomology. The same group of children are also less likely to be diagnosed with ADHD and treatment with stimulant medication is less likely. The review also focused on parent understanding of normal child development and behavior and parental beliefs about mental health care. Minority parents and caregivers also have less knowledge of common mental health conditions and their symptoms – one study found that African American parents and caregivers were less likely to have heard of ADHD, had exposure to information such as causes and treatment, or know someone with ADHD. Cultural beliefs, historical factors, and long-standing mistreatment can also influence minorities perception and access to healthcare and educational services. There is also a greater stigma tied to seeking

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services such as those that support an individual with developmental delay. Despite recommendations by the American Academy of Pediatrics (AAP), recent studies have shown that providers are less likely to ask Spanish-speaking Latino and African American parents about developmental concerns – this is also true for children that are at high risk of a developmental disorder. Additional disparities may occur when a child receives a referral from their primary care provider to a specialist (e.g., developmental-behavioral pediatrician, child psychiatrist, child psychologist). This includes decreased participation in early intervention services, especially in African American children.

National and Specialty Organizations

The **Bright Futures** / **AAP** Recommendations for Preventive Pediatric Health Care – Periodicity Schedule includes developmental screening and surveillance at 9, 18, and 30 months of age – screening for autism spectrum disorder is recommended at 18 and 24 months of age. In addition, behavioral, social, and emotional screening is recommended at each health maintenance visit.

The AAP also published the following clinical reports:

- Identification, Evaluation, and Management of Children With Autism Spectrum Disorder (Hyman et al., 2020)
- Promoting Optimal Development: Identifying Infants and Young Children With Developmental Disorders Through Developmental Surveillance and Screening (² Lipkin et al., 2020)
- School-Aged Children Who Are Not Progressing Academically: Considerations for Pediatricians (Rey-Casserly et al., 2019)
- School Readiness (Williams et al., 2019)
- Promoting Optimal Development: Screening For Behavioral and Emotional Problems (Weitzman et al., 2015)
- Comprehensive Evaluation of the Child With Intellectual Disability or Global Developmental Delays (Moeschler et al., 2014)
- Motor Delays: Early Identification and Evaluation (Noritz et al., 2013)

The **National Institute for Health and Care Excellence (NICE)** (2017) published a guideline titled *Developmental Follow-Up of Children and Young People Born Preterm* that focuses on the developmental follow-up of babies, children and young people under 18 years who were born preterm (before 37 weeks of pregnancy). In addition, the guideline discusses the risk of different developmental problems and disorders as well as additional assessments and support children born preterm may need during their development.

The **United States Preventive Services Task Force (USPSTF)** (2016) published a final recommendation statement on *Autism Spectrum Disorder in Young Children: Screening.* Screening for ASD in young children for whom no concerns have been raised by the child's parents, caregiver, or provider is not recommended. Note: At time of policy approval, an update was in progress.

SUPPLEMENTAL INFORMATION

Developmental	A heterogeneous group of conditions caused by impairments in learning, language,
Disabilities or	behavior, or motor skills. Includes intellectual disabilities, learning disorders, autism
Developmental	spectrum disorder, attention deficit hyperactivity disorder, cerebral palsy, and vision or
Disorders	hearing impairment.
Developmental	The process through which children who have developmental delay or are at risk for
Surveillance	developmental delay are identified. Occurs at preventive care visits and consists of eliciting parental or caregiver concerns, identifying risk and resilience factors, maintaining a developmental history, making direct observations of the child and caregiver-child interactions, documenting findings, and collaborating with other providers and professionals.

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Developmental	Refers to the use of a standardized test to identify asymptomatic children who are at risk
Screening	for a developmental disorder; children who screen positive should undergo a developmental-behavioral evaluation.
Developmental-	A comprehensive review and assessment of development and behavior to identify a
Behavioral Evaluation	developmental disorder and develop a treatment plan.
or Testing	
Intellectual Disability	A neurodevelopmental disorder that begins in childhood and is characterized by limitations in both intelligence and adaptive skills, affecting at least one of three adaptive domains (conceptual, social, and practical), with varying severity. This includes learning, problem-solving, adaptive skills development, and independence, generally with onset prior to age 18 years of age. Developmental deficits may be lifelong.

Sources: Khan & Leventhal, 2023; Aites & Schonwald, 2022; Pivalizza, 2022

CODING & BILLING INFORMATION

CDT Codos

CPT	Description
96112	Developmental test administration (including assessment of fine and/or gross motor, language, cognitive level, social, memory and/or executive functions by standardized developmental instruments when performed), by physician or other qualified health care professional, with interpretation and report; first hour
96113	Developmental test administration (including assessment of fine and/or gross motor, language, cognitive level, social, memory and/or executive functions by standardized developmental instruments when performed), by physician or other qualified health care professional, with interpretation and report; each additional 30 minutes (List separately in addition to code for primary procedure)

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HCPCS Code

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HCPCS	Description	
G0451	Development testing, with interpretation and report, per standardized instrument form	

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

4/13/2023 New policy

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APPENDIX

Reserved for State specific information. Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.

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