Molina Clinical Policy
Developmental Testing: Policy No. 432

Last Approval: 4/10/2024
Next Review Due By: April 2025

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

Developmental delay is when a child does not progress through predictable developmental phases/milestones as appropriate for their age. Developmental delays can manifest in multiple ways, such as delays in motor, cognitive, social, and emotional skills. There are many factors that can contribute developmental or intellectual delays, including teratogen exposure, prematurity and/or low birth weight, congenital or chromosomal anomalies, low socioeconomic status, lack of healthcare access, environmental toxin exposure, and other risk factors.

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, 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 2023).

Developmental screening is an important part of pediatric healthcare. Approximately 1 in 6 children ages 3 – 17 have a developmental disability, yet many are not identified before school age (Zablotsky et al. 2019). Developmental monitoring or surveillance should begin at birth, with robust parental education on how to assess their child's ability to meet milestones at the appropriate time. Involving the parents in developmental monitoring helps catch possibly delays, arrests, or regressions early. Appropriate screening tools should be employed at each well child/pediatric preventative visit to professionally assess a child's development. Universal developmental - behavioral screens should be conducted at 9 months, 18 months, 24 months, 30 months, 4 years, and/or any time caregivers or providers are concerned about the developmental progression of the child (Aites & Schonwald 2023).

Children who demonstrate a possible developmental delay or disability based on initial screening assessments should undergo a more comprehensive **developmental testing/evaluation**. The results of testing services are intended to inform needs for additional treatment planning or services. Official diagnosis of a developmental delay or disability as early as possible is necessary to provide the child with early intervention services and supportive resources. 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).

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 2024). The most frequently used validated screening tools are the Ages and Stages Questionnaire (ASQ), Denver Developmental Screening Test (DDST), and Parent's Evaluation of Developmental Status (PEDS) (Rah et al. 2023).

Early Intervention
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).

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).

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. According to the United States Department of Education (date unknown) over 8 million eligible infants, toddlers, children, and youth with disabilities received services in the 2022-2023 school year. Part B of IDEA addresses children and youth ages 3 through 21 receiving special education and related services. Part C addresses infants and toddlers from birth to age 2 years receiving early intervention services.

COVERAGE POLICY

Developmental Evaluations/Testing related to developmental delays or disabilities is **considered medically necessary** when **ALL** the following criteria are met:

1. Member is a pediatric client, less than 18 years of age*
2. A validated developmental screening tool, the score of which is documented in Member's medical record, established the possibility of intellectual and/or developmental delay, requiring further assessment for definitive diagnosis and intervention.
3. Testing is performed for <u>one or more</u> of the following reasons:
   a. Identify and diagnose intellectual and/or developmental delay
   b. Help clarify diagnostically complex and ambiguous cases
   c. Further evaluate a specific cognitive domain
   d. Determine educational placements and/or to tailor educational plans
   e. Determine pre-post comparisons after intervention (e.g., medication) or injury (e.g., head trauma).
4. Testing is performed by a board-certified developmental pediatrician, board-certified child neurologist, or clinical child or pediatric psychologist
5. Testing is performed using a current, criterion-referenced, validated, and/or standardized testing tool that targets the specific skill being evaluated, with results reported as objective, measurable data (e.g., scaled scores, T-

scores, standard scores, or percentiles).

6. A separate identifiable report is produced and placed in the medical record

* Refer to Appendix for State specific information and age requirements.

Additional Testing

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

1. Member's symptoms persist without improvement despite following prescribed treatments, and **ALL** the following are met:
   a) Requested number of hours or units for testing does not exceed the reasonable time necessary to address the clinical questions with the identified measures
   b) Testing techniques are:
      i. Validated for the proposed diagnostic question or treatment plan
      ii. Do not represent redundant measurements of the same domain
      iii. Validated for the age and population of the member.

Limitations and Exclusions

The following interventions are considered **not medically necessary** and will not be covered:

1. Preventive counseling for developmental delay risk factor reduction, 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

Aldharman et al. (2023) conducted a systematic review and meta-analysis on the implications of early diagnosis and intervention in the management of neurodevelopmental delay (NDD) in children. A total of 13 studies were included to reveal the Early Start Denver Model (ESDM) model improved the quality of life for NDD children, as well as LEAP (Learning Experience and Alternative Program for Preschoolers and Their Parents) and Leap (Learning, Engaging, and Playing), were found to improve behavioral, education, and social interventions in NDD children. The most effective interventions noted was quality parent child relationship enhanced the management of NDD, and telehealth interventions improved the medical and psychosocial management of NDD in children. The authors concluded that future research on NDD can help inform parental interventions to prevent future neurodevelopment conditions, and that the use of screening tools requires careful complementary and multidisciplinary clinical evaluation to enable early detection and intervention to optimize normal functioning.

Rah et al. (2023) conducted a systematic review and meta-analysis on the real-world accuracy of developmental screening tests. A total of 56 studies were included and revealed that the most used screening tests were the Ages and Stages Questionnaire (ASQ), Denver Developmental Screening Test (DDST), and Parent's Evaluation of Developmental Status (PEDS). The pooled sensitivity and specificity were 0.75 (95% CI = 0.69-0.80) and 0.76 (95% CI = 0.71-0.80), and the overall diagnostic accuracy of the total outcomes (area under the curve) was 0.80. There was high heterogeneity observed across the studies, which led to the recommendation for a standardized process of validating studies for diagnostic accuracy.

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 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. ([1] 2020) 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

National and Specialty Organizations

The **Centers for Disease Control (CDC)** in partner with the **American Academy of Pediatrics (AAP**) (Zubler et al. 2022) convened an expert working group to revise its developmental surveillance checklists. The revision included eliminating repeated milestones across age list, adding age 15- and 30-month checklists, clarifying vague verbiage, including milestones at ages where 75% of children would be expected to demonstrate said milestone (to discourage the "wait and see" approach), simplified milestones to allow observation/achievement of milestones across social, cultural, and ethnic backgrounds, and included information on developmental promotion and resources for those concerned. The revised milestone checklists guide the CDC's *Learn the Signs. Act Early.* program, which aims to clarify when additional developmental screenings are clinically indicated and increase the rate of early intervention.

The **AAP** *Preventative 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 the time of policy approval, an update was in progress.

SUPPLEMENTAL INFORMATION

Developmental Monitoring	Refers to the process of observing a child's development. Consists of parental/caregiver monitoring of milestones and addressing any concerns; often involves parents, grandparents, caregivers, early educators, and early childhood providers to monitor as well.
Developmental Screening	Standardized tests and/or questionnaires designed to assess a child's development. Developmental screenings are performed at every well child visit to monitor the child's development and catch any potential delays as early as possible. Additionally, 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. Children who screen positive for possible delays should undergo a full developmental evaluation/test.
Developmental-Behavioral Evaluation/ Testing	A comprehensive review and assessment of development and behavior to identify a developmental disorder and develop a treatment plan.
Developmental Disability	Any condition that causes impairments in learning, language, behavior, cognitive, social, emotional, and motor skills.
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.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Codes

Code	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)

HCPCS (Healthcare Common Procedure Coding System) Code

Code	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

04/10/2024 Policy reviewed. Coverage criteria updated to further specify which professionals may administer tests, how scoring should be reported, and removed stipulation for entire test to be administered to be covered. IRO peer reviewed on February 23, 2024, by a practicing physician board certified in General Pediatrics and Developmental-Behavioral Pediatrics.

04/13/2023 New policy.

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