

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 occurs when a child does not reach expected developmental phases/milestones at the appropriate age. Developmental delays can affect various areas including motor skills, cognition, social interactions, and emotional regulation. Several factors may contribute to developmental or intellectual delays, including exposure to teratogens, prematurity and/or low birth weight, genetic or chromosomal anomalies, socioeconomic disadvantages, limited access to healthcare, 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 due to greater awareness, better surveillance, improved screening methods, and advances in neonatal care (Aites & Schonwald 2024).

Developmental screening is an important part of pediatric healthcare, ensuring early identification of developmental disabilities and delays. Approximately 1 in 6 children between ages 3 and 17 has a developmental disability, yet many are not diagnosed until school age (Zablotsky et al. 2019). Early identification is essential for timely intervention and improving long-term outcomes. Developmental monitoring should start at birth, with parents educated on typical milestones and signs of potential delays. Standardized screening tools should be used during every well-child or pediatric preventative visit to ensure comprehensive assessment. Universal developmental and behavioral screenings are recommended at 9 months, 18 months, 24 months, 30 months, 4 years, or whenever concerns about a child's development arise (Aites & Schonwald 2024). These screenings help determine the need for additional treatment planning or services.

Comprehensive assessments rely on standardized, valid and reliable tools that align with the child's age and developmental level. Additional factors such as the child's language, culture, communication abilities, socioeconomic background, and disability profile should be considered. When necessary, appropriate referrals should be made for specialists and further evaluations to determine the child's educational needs and access to early intervention services (Pivalizza 2024). Commonly used validated screening tools include the Ages and Stages Questionnaire (ASQ), Denver Developmental Screening Test (DDST), and Parent's Evaluation of Developmental Status (PEDS) (Rah et al. 2023).

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Early Intervention provides essential services, education, and support to children with a diagnosed or suspected developmental delays. This includes children with:

- A diagnosed physical or mental condition with a high likelihood of causing developmental delays,
- An existing developmental delay or are at risk of one,
- A special need that could affect their development or learning.

Early Intervention Programs (EIPs) serve as the primary support system for children up to age 3, with each state offering specialized programs tailored to educational and therapeutic needs. These programs are designed to reduce the impact of developmental delays or disabilities by addressing key developmental areas including physical, cognitive, communication social/emotional, and adaptive skills. State-specific criteria determine eligibility for these services.

The Individuals with Disabilities Education Act (IDEA) was established to ensure all eligible children with disabilities receive free, appropriate public education, including access to special education and related services. According to the United States Department of Education, more than 8 million infants, toddlers, children, and youth with disabilities received services in the 2022-2023 school year. Part B of IDEA supports children and youth ages 3 to 21, while Part C focuses on infants and toddlers from birth to age 2 years, providing crucial early intervention services to support developmental progress.

COVERAGE POLICY

Developmental Evaluations/Testing related to developmental delays or disabilities may be **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 one or more 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

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- 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

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

Systematic Review and Meta-Analyses

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. The analysis included 13 studies, showing that the Early Start Denver Model (ESDM) model improved the quality of life for children with NDD. Additionally, the LEAP (Learning Experience and Alternative Program for Preschoolers and Their Parents) and Leap (Learning, Engaging, and Playing) programs were found to improve behavioral, education, and social outcomes. The analysis identified a strong parent-child relationship as the most effective factor in managing NDD, while telehealth interventions were shown to improve both medical and psychosocial care. The authors emphasized the need for further research to refine parental interventions aimed at preventing future neurodevelopmental conditions. They also highlighted the importance of using screening tools alongside multidisciplinary clinical evaluations to facilitate early detection and intervention, promoting optimal developmental outcomes.

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.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Meurer et al. (2022) examined the results of preventive screening assessment for over 30,000 children across three age groups: 8 to 12 months, 13 to 24 months, and 25 to 36 months. The study analyzed electronic health records (EHR) from 25 clinics and 150 providers in Wisconsin between April 2017 to April 2019. Over a 25-month period, screening rates across all age groups increased from 60% to over 95%. However, lower screening rates were observed among those enrolled in Medicaid, Black children, and children those residing in lower income zip codes. Significant differences were noted in responses to the ASQ (3rd ed.) based on gender, race/ethnicity, insurance status, and income level. Regardless of age group or insurance type, no significant differences were found in therapy continuation or referral rates.

The study also focused on quality improvement interventions. Clinics involved in the review implemented strategies such as appointing clinic champions, educating staff on the screening process and standardized tools, utilizing plan-do-study-act cycles, incorporating EHR prompts, offering financial incentives, and monitoring screening rates with control charts, including its completion before clinic visits. Providers suggested integrating the tool directly into the EHR, allowing parents or caregivers to complete it online before appointments. Additionally, providers cited the length of the ASQ as another challenge.

Lipkin et al. (1 2020) analyzed data from the American Academy of Pediatrics Periodic Survey conducted in 2002, 2009, and 2016, examining provider knowledge, attitudes, and practices related to developmental screening and referrals. The use of standardized developmental screening tools increased significantly, from 21% in 2002 to 63% in 2016. While referrals are crucial for assessing underlying causes and co-occurring conditions, only 46% of surveyed providers reported referring patients for speech and language delays, hearing loss, and neurogenetic conditions. The adoption of centralized electronic referral systems, patient navigators, tracking systems, and early intervention (EI) partnerships has improved referral rates to EI programs and services. However, inconsistent quality of EI programs

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remained a barrier, with concerns rising from 24% in 2002 to 30% in 2016. The most-reported obstacle in 2016 was the lack of program feedback (38%), highlighting the need for better communication between pediatricians and local EI specialists. The authors emphasized the importance of continuously improving referral systems, enhancing EI programs, and developing more effective methods for tracking child outcomes.

Lipkin et al. (2020) discuss a universal framework for the surveillance and screening of developmental conditions, including autism, hearing impairments, intellectual and motor disabilities, and behavioral disorders. This system integrates development surveillance during routine health supervision visits alongside standardized screening tests at 9, 18, and 30 months. Surveillance efforts involve collaboration with early childhood professionals in childcare centers, preschools, Head Start programs, and home visitation services, with a focus on parental engagement in developmental screening. The authors outline a 15-step algorithm for screening children without previously identified developmental concerns during health supervision visits:

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

National and Specialty Organizations

The **Centers for Disease Control (CDC)**, in collaboration with the **American Academy of Pediatrics (AAP)** convened an expert working group to update its developmental surveillance checklists (Zubler et al. 2022). The revisions included eliminating redundant milestones across age groups, introducing checklists for 15- and 30-month-olds, clarifying vague verbiage, and ensuring milestones reflect the ages at which at least 75% of children typically achieve them- discouraging the “wait and see” approach. Additionally, the updates simplified milestone descriptions to accommodate diverse social, cultural, and ethnic backgrounds, while incorporating information on developmental promotion and resources for concerned caregivers. The revised checklists inform the CDC’s *Learn the Signs. Act Early.* program, designed to help determine when additional developmental screenings are clinically indicated and promote early intervention.

The **AAP Preventative Care/Periodicity Schedule** recommends developmental screening and surveillance at 9, 18, and 30 months with autism spectrum disorder (ASD) screenings specifically advised at 18 and 24 months. In addition, behavioral, social, and emotional screenings are recommended at every routine health visit.

Additionally, the AAP has published several clinical reports on developmental screening and management, including:

- *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)

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The **National Institute for Health and Care Excellence (NICE)** (2017) published the guideline *Developmental Follow-Up of Children and Young People Born Preterm*, which focuses on monitoring the development of individuals under 18 who were born before 37 weeks of gestation. The guideline outlines the risks associated with preterm birth, discusses potential developmental challenges, and provides recommendation for additional assessments and support services.

The **United States Preventive Services Task Force (USPSTF)** (2016) published a final recommendation statement, *Autism Spectrum Disorder in Young Children: Screening*. The statement advised against routine ASD screening in children who do not exhibit concerns raised by parents, caregivers, or providers.

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)

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

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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

04/09/2025	Policy reviewed. No changes to coverage criteria. Updated Summary of Medical Evidence and References.
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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