

Policy # 00816

Original Effective Date: 01/01/2023 Current Effective Date: 01/13/2025

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

*Note:* Cognitive Rehabilitation is addressed separately in medical policy 00578.

# **Services Are Considered Investigational**

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers applied behavioral analysis for individuals who are 21 years of age and older with autism spectrum disorder to be **investigational.**\*

# **Background/Overview**

## **Autism Spectrum Disorder**

Autism spectrum disorder (ASD) is a biologically based neurodevelopmental disorder characterized by persistent deficits in social communication and social interaction and restricted, repetitive patterns of behavior, interests, and activities. ASD can range from mild social impairment to severely impaired functioning; as many as half of individuals with autism are non-verbal and have symptoms that may include debilitating intellectual disabilities, inability to change routines, and severe sensory reactions. The American Psychiatric Association's Diagnostic and Statistical Manual, Fifth Edition (DSM-5) provides standardized criteria to help diagnose ASD. Autism can co-occur with other mental health diagnoses, including, but not limited to, depression, anxiety disorders (eg, social anxiety, obsessive-compulsive disorder), attention deficit hyperactivity disorder, Tourette syndrome/tic disorder, personality disorder, and/or psychosis.

Diagnosis of ASD in the United States (U.S.) generally occurs in 2 steps: developmental screening followed by comprehensive diagnostic evaluation if screened positive. The American Academy of Pediatrics (AAP) recommends general developmental screening at 9, 18, and 30 months of age and ASD-specific screening at 18 and 24 months of age. Diagnosis and treatment in the first few years of life can have a strong impact on functioning since it allows for treatment during a key window of developmental plasticity. However, early diagnosis in the US remains an unmet need even though studies have demonstrated a temporal trend of decreasing mean age at diagnosis over time.

ASD is a lifelong condition; however, relatively little work has investigated the most effective treatments in adults. Per a study from the Centers for Disease Control and Prevention (CDC), an

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estimated 5,437,988 adults (2.21%) in the U.S. have ASD, with many requiring ongoing services and support. Treatments for ASD can be generally broken down into the following categories, although some treatments involve more than one approach: behavioral, developmental, educational, social-relational, pharmacological, psychological, and complementary/alternative. The gold standard therapy for the core symptoms of ASD is behavioral therapy. Additionally, many individuals with ASD have abnormalities in multiple organs (eg, brain, immune system, gastrointestinal system) and may be adversely impacted by environmental factors including psychosocial stress, dietary limitations, and allergen exposure. Although it is unclear whether these issues are related to the etiology of ASD, there is evidence that these factors can alter ASD symptoms, which makes them potential therapeutic targets.

## **Applied Behavior Analysis**

ABA focuses on the analysis, design, implementation, and evaluation of social and other environmental modifications to produce meaningful changes in human behavior and includes the use of direct observation, measurement, and functional analysis of the relationship between environment and behavior. ABA uses changes in environmental events, including antecedent stimuli and consequences, to produce practical and significant changes in behavior. These relevant environmental events are usually identified through a variety of specialized assessment methods. ABA is based on the fact that an individual's behavior is determined by past and current environmental events in conjunction with organic variables such as genetic endowment and physiological variables. When applied to ASD, ABA focuses on treating the problems of the disorder by altering the individual's social and learning environments.

ABA treatment models can generally be classified as focused or comprehensive. Focused ABA refers to treatment provided directly to the individual for a limited number of behavioral targets and may involve increasing socially appropriate behavior or reducing problem behavior as the primary target. Focused ABA is appropriate for individuals who need treatment only for a limited number of key functional skills or have such acute problem behavior that its treatment should be the priority. Comprehensive ABA refers to treatment of the multiple affected developmental domains (eg, cognitive, communicative, social, emotional, and adaptive functioning) and maladaptive behaviors. Initially, treatment is typically provided in structured therapy sessions, which are integrated with more naturalistic methods as appropriate. As the individual progresses and meets established criteria for participation in different settings, treatment in those settings and in the larger community should be provided.

# FDA or Other Governmental Regulatory Approval

**U.S. Food and Drug Administration (FDA)** 

ABA is not subject to regulation by the U.S. Food and Drug Administration.



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## Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Autism spectrum disorder (ASD) is a lifelong biologically based neurodevelopmental disorder characterized by persistent deficits in social communication and social interaction and restricted, repetitive patterns of behavior, interests, and activities. Applied behavior analysis (ABA) is therapeutic approach comprised of multiple techniques in which environmental variables are identified that influence socially significant behavior and are used to develop individualized and practical strategies to teach basic skills such as communication, adaptive skills, or social interactions. ABA therapy may be performed by, or supervised by, a certified ABA provider, such as a a licensed applied behavior analyst (LABA) or a trained, licensed psychologist. Clinical guidance has identified ABA and/or other developmental and naturalistic approaches as examples of potential components to include in a Comprehensive Treatment Model in children with ASD. ABA is also being evaluated to aid in the treatment of ASD into adulthood.

#### **Summary of Evidence**

For individuals ≥18 years of age with ASD who receive ABA, the evidence includes a systematic review of 13 studies of various psychosocial interventions. Relevant outcomes are symptoms, functional outcomes, and quality of life. Because there are no comparative studies on ABA for individuals who are ≥18 years of age with ASD, it is not possible to determine with confidence whether ABA improves symptoms, quality of life, or functional impairment. Among the 13 total studies, the single systematic review included 5 single case studies of 5 individuals ≥18 years of age with ASD and coexisting developmental disorders evaluating various focused ABA interventions. Although the results from all the case studies were positive in nature, they are significantly limited by imprecision (N=5) and the lack of comparison to an established alternative treatment using an outcome measurement instrument with a prespecified clinically significant difference. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

# **Supplemental Information**

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

#### **Practice Guidelines and Position Statements**

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given



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to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

#### **National Institute for Health and Care Excellence**

NICE issued a clinical guideline on the diagnosis and management of autism spectrum disorder (ASD) in adults in 2012, which was last updated in June 2021. The NICE guidance provides recommendations for general principles of care; identification and assessment; identifying the correct interventions and monitoring their use; interventions for autism, behavior that challenges, and coexisting mental disorders; assessment and interventions for families, partners, and carers; and organization and delivery of care. Applied behavior analysis is not specifically mentioned but rather various psychosocial interventions are recommended for the core features of autism, to improve life skills, for challenging behaviors, and for those with concurrent mental disorders.

#### **U.S. Preventive Services Task Force Recommendations**

No U.S. Preventive Services Task Force (USPSTF) recommendations for ASD in adults have been identified.

### **Medicare National Coverage**

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

#### **Ongoing and Unpublished Clinical Trials**

A search of ClinicalTrials.gov in August 2024 did not identify any ongoing or unpublished trials that would likely influence this review.

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# **Policy History**

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12/01/2022 Medical Policy Committee review

12/14/2022 Medical Policy Implementation Committee approval. New policy.

12/07/2023 Medical Policy Committee review

12/13/2023 Medical Policy Implementation Committee approval. No change to coverage.

12/05/2024 Medical Policy Committee review

12/11/2024 Medical Policy Implementation Committee approval. Coverage eligibility

unchanged.

Next Scheduled Review Date: 12/2025

\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
  - 1. Consultation with technology evaluation center(s);



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- 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
- 3. Reference to federal regulations.

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**NOTICE:** If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

**NOTICE:** Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

