Sensory integration therapy and auditory integration therapy are considered investigational.

CPT code 97533 explicitly identifies sensory integrative therapy:
- **97533**: Sensory integrative techniques to enhance sensory processing and promote adaptive responses to environmental demands, direct (one-on-one) patient contact, each 15 minutes

The code above may also be used for auditory integration therapy.

Sensory integration therapy (SIT) has been proposed as a treatment of developmental disorders in patients with established dysfunction of sensory processing, particularly autism spectrum disorder. SIT may be offered by occupational and physical therapists who are certified in SIT. Auditory integration therapy (AIT) uses gradual exposure to certain types of sounds to improve communication in a variety of developmental disorders, particularly autism.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Sensory integration therapy is a procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration. No devices designed to provide AIT have been cleared for marketing by the Food and Drug Administration.

The goal of sensory integration therapy is to improve how the brain processes and adapts to sensory information, as opposed to teaching specific skills. Therapy usually involves activities that
provide vestibular, proprioceptive, and tactile stimuli, which are selected to match specific sensory processing deficits of the child. For example, swings are commonly used to incorporate vestibular input, while trapeze bars and large foam pillows or mats may be used to stimulate somatosensory pathways of proprioception and deep touch. Tactile reception may be addressed through a variety of activities and surface textures involving light touch.

Auditory integration therapy (AIT; also known as auditory integration training, auditory enhancement training, audio-psycho-phonology) involves having individuals listen to music modified to remove frequencies to which they are hypersensitive, with the goal of gradually increasing exposure to sensitive frequencies. Although several methods of AIT have been developed, the most widely described is the Berard method, which involves two, half-hour sessions per day separated by at least three hours, over ten consecutive days, during which patients listen to recordings. AIT has been proposed for individuals with a range of developmental and behavioral disorders, including learning disabilities, autism spectrum disorder, pervasive developmental disorder, and attention-deficit/hyperactivity disorder. Other methods include the Tomatis method, which involves listening to electronically modified music and speech, and Samonas Sound Therapy, which involves listening to filtered music, voices, and nature sounds.1

**Literature Review**

This review was informed by a Blue Cross Blue Shield Association Technology Evaluation Center (TEC) Assessment (1999) that evaluated sensory integration therapy (SIT).2

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life (QOL), and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens, and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, two domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

**Sensory Integration Therapy**

**Clinical Context and Purpose**

The purpose of SIT in patients who have developmental disorders is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is does the use of SIT in patients who have developmental disorders improve net health outcomes?

The following PICOTS were used to select literature to inform this review.

**Patients**

The relevant population(s) of interest are patients with developmental disorders.
Interventions
The treatment being considered is the use of SIT. The treatment sessions are often provided as part of a comprehensive occupational therapy or cognitive rehabilitation therapy and may last for more than one year.

Comparators
The following practices are currently being used to treat developmental disorders; specialized developmentally appropriate interventions for specific developmental disorders.

Outcomes
The general outcomes of interest are symptoms, change in disease status, functional outcomes and QOL.

Timing
Follow-up of at least six months would be desirable to assess outcomes.

Setting
Treatment sessions are usually delivered in a one-on-one setting by occupational therapists with special training from university curricula, clinical practice, and mentorship in the theory, techniques, and assessment tools unique to SIT. Organizations like Western Psychological Services currently offer certification for SIT.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:
  a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs
  b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies
  c. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought
  d. Studies with duplicative or overlapping populations were excluded.

Schaaf et al (2014) published an overview of current measurement issues in sensory integration. They proposed several changes to the outcomes used in sensory integration research, as follows:
  • “Additional measures ... to ensure a comprehensive assessment of the sensory and motor factors that may be influencing function and participation”;
  • “Assessment measures ... to address a wider age range”
  • Neurophysiologic studies.
  • “Fidelity to the core principles of SIT”
  • “studies ... to evaluate the dosage of therapy to understand the best candidates for intervention and the appropriate intensity and frequency of intervention”;
  • “Outcomes that are meaningful to clients and sensitive to the changes observed after intervention.”

The Sensory Processing Disorders Scientific Workgroup (2007) has also discussed the methodologic challenges of conducting intervention effectiveness studies of dynamic interactional processes, the lack of scientific evidence to support current practice, and methods for improving the quality of research in this area.

Systematic Reviews
Several systematic reviews have addressed the use of SIT in various clinical conditions. Four of the six systematic reviews included in this evidence review pertain to studies evaluating SIT for autism spectrum disorder (ASD), while the other two include a broader range of developmental disabilities.
The TEC Assessment (1999) compared the outcomes of SIT with those of standard occupational or physical therapy among children with ASD, cognitive disorders, or learning disabilities. One study identified evaluated the use of SIT in patients with ASD, which was noted to be limited by its lack of a control group. Three studies identified evaluated the use of SIT in patients with cognitive disorders, which were noted to be inconsistent in their results on the superiority of SIT. Eleven studies identified evaluated SIT in patients with learning disabilities or motor delay, including, in total, more than 600 children with a learning disability. Studies that used random assignment and blinded assessors suggested that SIT was not superior to conventional therapy and, in many cases, was not demonstrably superior to any treatment at all.

Case-Smith et al (2015) updated a systematic review on sensory processing interventions, including SIT, which they defined as clinician-based interventions that use sensory-rich, child-directed activities to improve a child’s adaptive responses to sensory experiences, and sensory-based interventions (defined as adult-directed sensory modalities applied to the child to improve behavior associated with modulation disorders), for children with ASD with concurrent sensory processing problems. This review was designed to focus on interventions that activate the somatosensory and vestibular systems for patients with ASD with co-occurring sensory processing problems. Nineteen studies published since 2000 were included, 5 of which evaluated SIT in patients with ASD and sensory processing disorders. Two studies reviewed were RCTs; both were small (n=20 and n=17 in the SIT groups). Reviewers noted the studies showed low or low-to-moderate effects and concluded that “It is premature to draw conclusions as to whether SIT for children with ASD, which is designed to support a child’s intrinsic motivation and sense of internal control, is ultimately effective.”

Brondino et al (2015) published a systematic review of complementary and alternative therapies for autism, which included SIT and auditory integration therapy (AIT). Regarding SIT for ASD treatment, reviewers identified 4 trials, including the RCT reported by Pfeiffer et al (2016; described below), and additional studies published in 1983, 2008, and 2011, with sample sizes of 18, 30, and 50, respectively. All four studies reported significant improvements in autistic core symptoms, including communication, social reciprocity, and motor activity. However, reviewers noted that two studies did not use a standardized form of SIT, and two did not use standardized outcome measures.

Watling and Hauer (2015) published a systematic review of Ayres Sensory Integration (ASI) and sensory-based interventions for individuals with ASD. Reviewers described ASI as a play-based method that “uses active engagement in sensory-rich activities to elicit the child’s adaptive responses and improve the child’s ability to successfully perform and meet environmental challenges.” The therapy is individualized by the therapist in response to an initial assessment. Sensory-based interventions are described as “applying adult-directed sensory modalities to the child with the aim of producing a short-term effect on self-regulation, attention, or behavioral organization.” Twenty-three articles met reviewers’ inclusion criteria, three of which were systematic reviews and five of which were RCTs. Overall, 4 studies evaluated ASI and the remaining 18 evaluated sensory-based interventions. Of the 4 studies evaluating ASI, 3 were RCTs, including the trials by Pfeiffer et al (2016) and Schaaf et al (2014; described below). Findings from one RCT included significant improvement in individualized goals, improved sleep, decreased ASD mannerisms, and reduced caregiver burden.

Case-Smith and Arbesman (2008) reviewed the evidence for SIT as part of a systematic review of interventions for ASD used in occupational therapy. Reviewers identified a level I study, which was a 2002 systematic review that had found only lower quality evidence (levels III and IV, with small sample sizes and lack of control groups), suggesting that sensory integration intervention was associated with positive changes in social interaction, purposeful play, and decreased sensitivity. Reviewers concluded: “although each of these studies had positive findings, when combined, the evidence remains weak and requires further study.”
May-Benson and Koomar (2010) published a systematic review of SIT, identifying 27 research studies (13 randomized trials) that met their inclusion criteria. Most studies had been performed with children who had learning or reading disabilities; there were two case reports/small series on the effect of SIT in children with ASD. Reviewers concluded that although the sensory integration approach might result in positive outcomes, findings were limited because of small sample sizes, variable intervention dosages, lack of fidelity to interventions, and selection of outcomes that might not be meaningful or might not change with the treatment provided.

**Randomized Controlled Trials**

Schaaf et al (2014) reported on results from a randomized trial of a manualized intervention for sensory difficulties in children with ASD. The trial enrolled 32 children from a convenience sample of eligible families with children ages 4 to 8 years who had a diagnosis of ASD and demonstrated difficulty processing and integrating sensory information as measured by the Sensory Profile or the Sensory Integration and Praxis Test. Subjects were randomized to usual care or to an intervention described as following the principles of ASI. The intervention was delivered by three licensed occupational therapists experienced working with children with ASD. The primary outcome was Goal Attainment Scaling, a systematic process for identifying goals relevant to individuals and their families that has been used to evaluate patients with ASD. Sample goals include: “Improve auditory process as a basis for sleeping through the night without getting out of bed for 7-8 h per night” and “Decrease oral sensitivity and will try 5 new foods.” Each goal is associated with a scale for level of attainment. For the primary outcome, the intervention group had a significantly higher goal achievement score than the control group (mean, 56.53 [n=17] vs 42.72 [n=14], p=0.003). Change in functional skills did not differ significantly between groups but intervention group subjects had significantly greater improvements in the 2 subscales of self-care/caregiver assistance (p=0.008) and social function/caregiver assistance (p=0.039). The groups did not differ in terms of autistic or adaptive behaviors. Strengths of this trial were its use of a protocolized intervention and its attempt to use an outcome measure relevant to patients and families. However, replication of this trial in a larger sample of patients is required.

A pilot study by Pfeiffer et al (2011) randomized 37 children with a sensory processing disorder (21 with ASD, 16 with pervasive developmental disorder not otherwise specified) to sensory integration interventions or to fine motor interventions (18 treatments over 6 weeks). Fidelity to sensory integration interventions was verified with a fidelity measure developed for research by Parham et al (2007). Blinded evaluation at the conclusion of the intervention found no significant differences between the two groups on the Quick Neurological Screening Test or sensory processing scores, except for the autistic mannerisms (e.g., stereotyped or self-stimulatory behavior) subscale. The sensory integration group demonstrated greater improvement than the fine motor group on individualized Goal Attainment Scaling scores. Post hoc analysis found that more children in the SIT group were able to complete parts of the standardized Quick Neurological Screening Test after the intervention. This finding is limited by the post hoc analysis and differences between the groups at baseline.

Members of the Sensory Processing Disorders Scientific Workgroup (2007) reported on the results from a single-institution randomized pilot study for a proposed multicenter trial. Thirty families agreed to participate over a three-year period. The children had a clinical diagnosis of sensory modulation disorder following a comprehensive evaluation with standardized and clinical testing (including responses to sensory stimuli, attempts by the child to self-regulate, behavioral disorganization, and somatic responses to the testing situations). The 24 children who began treatment were randomized to 1 of 3 groups consisting of occupational therapy with sensory integration (2 times per week for 10 weeks, n=7), equivalent activity control sessions (n=10), or a waiting-list control group (n=7). Functional improvements were assessed using five validated/standardized parent rating scales. Significant improvements relative to both control groups were obtained for Goal Attainment Scaling. A number of the other outcome measures (Leitner International Performance Scale, Short Sensory Profile, Internalizing on the Child Behavior Checklist) showed trends for improvement.
Uyanik et al (2003) reported on a study of 45 children with Down syndrome allocated to 3 treatment groups (SIT alone, vestibular stimulation plus SIT, neurodevelopmental therapy). Greater improvements in outcomes for the vestibular stimulation plus SIT group and in the neurodevelopmental therapy group than for the SIT alone group were reported.14 Outcomes assessed were the Ayres Southern California Sensory Integration Test, Pivot Prone Test, Gravitational Insecurity Test, and Pegboard Test, along with physical assessment. The authors concluded that all methods of treatment should be considered when planning rehabilitation therapies for children with Down syndrome, even though SIT alone was not shown to be superior to the other therapy groups.

Section Summary: Sensory Integration Therapy
The most direct evidence related to outcomes from SIT comes from randomized trials and systematic reviews of these trials. Although certain studies demonstrated some improvements on subsets of the outcomes measured, the studies were limited by small sample sizes, heterogeneous patient populations, and variable outcome measures. As a result, the evidence is not sufficiently robust to draw conclusions about the effect of, and the most appropriate patient populations for, SIT.

Auditory Integration Therapy
Clinical Context and Purpose
The purpose of AIT in patients who have developmental disorders is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is; does the use of AIT in patients who have developmental disorders improve net health outcomes?

The following PICOTS were used to select literature to inform this review.

Patients
The relevant population(s) of interest are patients with developmental disorders. Although AIT has been proposed as a therapy for a number of neurobehavioral disorders, the largest body of evidence, including systematic reviews, relates to its use in ASD.

Interventions
The treatment being considered is the use of AIT.

Comparators
The following practices are currently being used to treat developmental disorders; specialized interventions for specific developmental disorders.

Outcomes
The general outcomes of interest are symptoms, change in disease status, functional outcomes and QOL.

Timing
Follow-up of at least six months would be desirable to assess outcomes.

Setting
Treatment sessions are usually delivered in a one-on-one setting by therapists with special training.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

a. To assess efficacy, outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.

c. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

d. Studies with duplicative or overlapping populations were excluded.

A Cochrane review (2011) evaluated AIT along with other sound therapies for ASD. Included were 6 RCTs on AIT and 1 on Tomatis therapy, comprising a total of 182 subjects (age range, 3-39 years). For most trials, the control condition was listening to unmodified music for the same amount of time as the active treatment group. Allocation concealment was inadequate for all trials, and 5 trials had fewer than 20 participants. Meta-analyses could not be conducted. Three studies did not demonstrate any benefit of AIT over control conditions, and three studies had outcomes of questionable validity or outcomes that were not statistically significant. Reviewers found no evidence that AIT is an effective treatment for ASD; however, evidence was insufficient to prove that it is not effective.

In the systematic review examining complementary and alternative therapies for ASD, Brondino et al (2015) identified the same 6 RCTs of AIT included in the 2011 Cochrane review. Like the Cochrane review, Brondino et al (2015) concluded that the largest studies did not report improvements with AIT.

A 2010 systematic review of therapies for ASD evaluated the evidence for AIT. The reviewer identified a 2002 systematic review (an early version of the Cochrane review by Sinha et al [2011]; previously discussed), which identified no RCTs meeting the author’s inclusion criteria, and no subsequent RCTs or cohort studies comparing AIT with usual care.

Rossignol (2009) conducted a systematic review of novel and emerging treatments for ASD, including AIT. Reviewers identified 1, 3-month, double-blind, controlled study of AIT in 17 individuals with autism, which demonstrated significant decreases in irritability, stereotypy, hyperactivity, and excessive speech in patients in the AIT group. The study also examined an earlier version of the Cochrane review by Sinha et al (2011). Overall, Rossignol (2009) concluded there was grade C evidence related to the use of AIT for ASD.

Section Summary: Auditory Integration Therapy

The largest body of evidence on the use of AIT relates to treatment of ASD. A 2011 Cochrane review and several earlier systematic reviews generally found that studies of AIT failed to demonstrate meaningful clinical improvements. No subsequent comparative studies of AIT were identified.

Summary of Evidence

For individuals who have developmental disorders who receive SIT, the evidence includes RCTs, systematic reviews of these trials, and case series. The relevant outcomes are functional outcomes and QOL. Due to the individualized approach to SIT and the large variations in patients’ disorders, large multicenter RCTs are needed to evaluate the efficacy of this intervention. The most direct evidence on SIT outcomes derives from several randomized trials. Although some of these trials demonstrated improvements for subsets of outcomes measured, they had small sample sizes, heterogeneous patient populations, and variable outcome measures. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have developmental disorders who receive AIT, the evidence includes several RCTs and systematic reviews of these trials. The relevant outcomes are functional outcomes and QOL. For AIT, the largest body of literature relates to its use in ASD. Several systematic reviews of AIT in the treatment of autism have found limited evidence to support its use. No comparative studies identified evaluated use of AIT for other conditions. The evidence is insufficient to determine the effects of the technology on health outcomes.
Supplemental Information
Practice Guidelines and Position Statements

Sensory Integration Therapy
American Academy of Pediatrics
A policy statement by the American Academy of Pediatrics (2012) on SIT for children with developmental and behavioral disorders stated that “[o]ccupational therapy with the use of sensory-based therapies may be acceptable as one of the components of a comprehensive treatment plan. However, parents should be informed that the amount of research regarding the effectiveness of sensory integration therapy is limited and inconclusive.” The Academy indicated that these limitations should be discussed with parents, along with instruction on how to evaluate the effectiveness of a trial period of SIT.

American Occupational Therapy Association
The AOTA (2009) stated that “AOTA recognizes SI [sensory integration] as one of several theories and methods used by occupational therapists and occupational therapy assistants working with children in public and private schools” to improve a child’s “ability to access the general education curriculum” and to participate in school-related activities.

The AOTA (2011) published evidence-based occupational therapy practice guidelines for children and adolescents with challenges in sensory processing and sensory integration. The AOTA gave a level C recommendation for SIT for individual functional goals for children, for parent-centered goals, and for participation in active play in children with sensory processing disorder, and to address play skills and engagement in children with autism. A level C recommendation is based on “…weak evidence that the intervention can improve outcomes, and the balance of the benefits and harms may result either in a recommendation that occupational therapy practitioners routinely provide the intervention … or in no recommendation because the balance of the benefits and harm is too close to justify a general recommendation.” Specific performance skills evaluated were motor and praxis skills, sensory-perceptual skills, emotional regulation, and communication and social skills. There was insufficient evidence to recommend SIT for academic and psychoeducational performance (e.g., math, reading, written performance).

U.S. Preventive Services Task Force Recommendations
Not applicable.

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
Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

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<th>NCT No.</th>
<th>Trial Name</th>
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<th>Completion Date</th>
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<td>NCT02536365</td>
<td>Sensory Integration Therapy in Autism: Mechanisms and Effectiveness</td>
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<td>Oct 2020</td>
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NCT: national clinical trial.
References


### Documentation for Clinical Review

- No records required

### Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.

#### IE

The following services may be considered investigational.

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<th>Type</th>
<th>Code</th>
<th>Description</th>
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<td>CPT®</td>
<td>97533</td>
<td>Sensory integrative techniques to enhance sensory processing and promote adaptive responses to environmental demands, direct (one-on-one) patient contact, each 15 minutes</td>
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<tr>
<td>HCPCS None</td>
<td></td>
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<tr>
<td>ICD-10 Procedure None</td>
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### Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

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<th>Effective Date</th>
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<td>06/07/2000</td>
<td>BCBSA Medical Policy adoption</td>
<td>Medical Policy Committee</td>
</tr>
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<td>04/01/2001</td>
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<td>01/11/2008</td>
<td>Policy reviewed, updated with BCBSA; no change in position</td>
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<td>08/23/2013</td>
<td>Policy revision without position change. Policy placed on No Further Routine Literature Review and Update status.</td>
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<td>06/30/2015</td>
<td>Coding update</td>
<td>Administrative Review</td>
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<td>05/01/2016</td>
<td>Policy title change from Sensory Integration Therapy</td>
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### Definitions of Decision Determinations

**Medically Necessary:** A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with the best available evidence.
with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

**Prior Authorization Requirements (as applicable to your plan)**

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. 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 covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.