



Louisiana

Sensory Integration Therapy and Auditory Integration Therapy

Policy # 00174

Original Effective Date: 08/24/2005

Current Effective Date: 10/17/2018

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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 sensory integration (SI) therapy and auditory integration therapy to be **investigational**.*

Background/Overview

The goal of SI therapy is to improve the way 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.

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 SI theory. Two organizations currently offer certification for SI therapy; Sensory Integration International, a nonprofit branch of the Ayres Clinic in Torrance, California, and Western Psychological Services, a private organization that has a collaborative arrangement with University of Southern California (USC), Los Angeles, to offer sensory integration training through USC's Department of Occupational Science and Therapy. The sessions are often provided as part of a comprehensive occupational therapy or cognitive rehabilitation therapy and may last for more than 1 year.

AI therapy (also known as AI training, auditory enhancement training, audio-psycho-phonology) is another method that relies on gradual exposure to sound to which individuals are sensitive, based on having individuals listen to music that has been modified to remove frequencies to which the individual is hypersensitive. Although several methods have been developed, the most widely-described is the Berard method, which involves 2 half-hour sessions per day separated by at least 3 hours, over 10 consecutive days, during which patients listen to recordings. AI training has been proposed for individuals with a range of developmental and behavioral disorders, including learning disabilities, autism spectrum disorders, pervasive developmental disorder, attention deficit and 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.

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FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

SI therapy is a procedure and, as such, is not subject to regulation by the U.S. FDA. There are no devices designed to provide AI therapy that have clearance for marketing from FDA.

Centers for Medicare and Medicaid Services (CMS)

There is no national coverage determination (NCD) for sensory integration therapy. In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

Rationale/Source

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to 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 a technology, 2 domains are examined: the relevance and the 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

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”;

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- “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 6 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 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 clinic-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 behaviors 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, five 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 that 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 2016 RCT reported by Pfeiffer et al (described below), and additional studies published in 1983, 2008, and 2011, with sample sizes of 18, 30, and 50, respectively. All 4 studies reported significant improvements in autistic core symptoms, including communication, social reciprocity, and motor

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activity. However, reviewers noted that 2 studies did not use a standardized form of SIT, and 2 did not use standardized outcome measures.

Also, 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, three were RCTs, including the trials by Pfeiffer et al and Schaaf et al (described below). Findings from 1 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 2 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

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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 2 groups on the Quick Neurological Screening Test or sensory processing scores, except for the autistic mannerisms (eg, 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.

In 2007, members of the Sensory Processing Disorders Scientific Workgroup reported on results from a single-institution randomized pilot study for a proposed multicenter trial. Thirty families agreed to participate over a 3-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 parental 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.

In a study of 45 children with Down syndrome allocated to 3 treatment groups (SIT alone, vestibular stimulation plus SIT, neurodevelopmental therapy), Uyanik et al (2003) reported greater improvements in outcomes for the vestibular stimulation plus SIT group and in the neurodevelopmental therapy group than

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for the SIT alone group. 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 effects of, and the most appropriate patient populations for, SIT.

AUDITORY INTEGRATION THERAPY

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.

A Cochrane review (2011) evaluated AIT along with other sound therapies for ASD. Included were 6 RCTs on AIT and one 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 3 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; described above) identified the same 6 RCTs of AIT included in the 2011 Cochrane review. Like the Cochrane review, Brondino et al 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 2011 Cochrane review by Sinha et al, 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 one 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 2011 Cochrane review by Sinha. Overall, Rossignol concluded that there was grade C evidence related to the use of AIT for ASD.

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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 randomized controlled trials, systematic reviews of these trials, and case series. Relevant outcomes are functional outcomes and quality of life. 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 small 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 randomized controlled trials and systematic reviews of these trials. Relevant outcomes are functional outcomes and quality of life. For AIT, the largest body of literature relates to its use in autism spectrum disorder. 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.

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|------------|---|
| 08/03/2005 | Medical Director review |
| 08/16/2005 | Medical Policy Committee review |
| 08/24/2005 | Managed Care Advisory Council approval |
| 09/05/2007 | Medical Director review |
| 09/19/2007 | Medical Policy Committee approval. Addition of FDA and or other governmental regulatory approval. Policy statement unchanged. |
| 09/03/2009 | Medical Policy Committee review |
| 09/16/2009 | Medical Policy Implementation committee approval. Coverage eligibility unchanged. |
| 09/09/2010 | Medical Policy Committee review |
| 09/15/2010 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 09/01/2011 | Medical Policy Committee review |
| 09/14/2011 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 10/11/2012 | Medical Policy Committee review |
| 10/31/2012 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 10/03/2013 | Medical Policy Committee review |
| 10/16/2013 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 10/02/2014 | Medical Policy Committee review |
| 10/15/2014 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 10/08/2015 | Medical Policy Committee review |

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10/21/2015 Medical Policy Implementation Committee approval. Auditory integration therapy added as investigational and added to the title.
 10/06/2016 Medical Policy Committee review
 10/19/2016 Medical Policy Implementation Committee approval. No change to coverage.
 01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
 10/05/2017 Medical Policy Committee review
 10/18/2017 Medical Policy Implementation Committee approval. No change to coverage.
 10/04/2018 Medical Policy Committee review
 10/17/2018 Medical Policy Implementation Committee approval. No change to coverage
 Next Scheduled Review Date: 10/2019

Coding

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