Sensory Integration Therapy and Auditory Integration Therapy

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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.
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

Sensory Integration Therapy
The literature related to the use of SI therapy consists primarily of small case series, along with a smaller number of comparative studies and systematic reviews. Given the individualized nature of SI therapy and the potential for confounding due to effects of treatment other than the SI therapy itself, large comparative studies are needed to demonstrate effectiveness.

In 2014, Schaaf et al published an overview of current measurement issues in the area of sensory integration (SI). The authors propose several changes to the outcomes used in SI 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 sensory integration therapy (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 has 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, while the other 2 include a broader range of developmental disabilities.

The 1999 TEC Assessment compared the outcomes of sensory SIT with that of standard occupational/physical therapy among children with autism, mental retardation, or learning disabilities. One study was identified that evaluated the use of SIT in patients with autism, which was noted to be limited by
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its lack of a control group. Three studies were identified that evaluated the use of SIT in patients with mental retardation, which were noted to be inconsistent in their results regarding the superiority of SIT. Eleven studies were identified that 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 even demonstrably superior to any treatment at all.

In 2015, Case-Smith et al published an updated systematic review of 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 that are applied to the child to improve behaviors associated with modulation disorders), for children with autism spectrum disorder (ASD) with concurrent sensory processing problems. This review was designed to focus on interventions that activate the somatosensory and vestibular systems for patients with autism 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 randomized controlled trials (RCTs), which were small (N=20 and N=17 in the sensory integration groups); the authors 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.”

In 2015, Brondino et al published a systematic review of complementary and alternative therapies for autism, which included SIT and auditory integration therapy (AIT). Regarding SIT for autism treatment, the authors identified 4 trials, including the 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 activity. However, the reviewers noted that 2 studies did not use a standardized form of SIT, and 2 did not use standardized outcome measures.

Also in 2015, Watling and Hauer published a systematic review of Ayres Sensory Integration (ASI) and sensory-based interventions for individuals with ASD. The authors describe 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 the authors’ inclusion criteria, 3 of which were systematic reviews and 5 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 studies by Pfeiffer et al and Schaaf et al described below. Findings from 1 RCT included significant improvement in individualized goals, improved sleep, decreased autism mannerisms, and reduced caregiver burden.

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In 2008, Case-Smith and Arbesman reviewed the evidence for SIT as part of a systematic review of interventions for autism used in occupational therapy in 2008. The authors identified a level-1 study, which was a systematic review from 2002 that had found only lower quality evidence (levels I II and IV, with small sample sizes and a lack of control groups), suggesting that SI intervention was associated with positive changes in social interaction, purposeful play, and decreased sensitivity. The authors concluded: “although each of these studies had positive findings, when combined, the evidence remains weak and requires further study.”

May-Benson and Koomar published a systematic review of SIT in 2010. The review identified 27 research studies (13 randomized trials) that met their inclusion criteria. Most studies had been performed in children with learning or reading disabilities; there were 2 case reports/small series on the effect of SIT in children with autism. The review concluded that although the SI approach may result in positive outcomes, findings may be limited because of small sample sizes, variable intervention dosage, lack of fidelity to intervention, and selection of outcomes that may not be meaningful or may not change with the treatment provided.

**Controlled Trials**

In 2014, Schaaf et al reported results from a randomized trial of a manualized intervention for sensory difficulties in children with autism. The study enrolled 32 children from a convenience sample of eligible families with children aged 4 to 8 years who had a diagnosis of autism 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 sensory integration outlined by Ayres. The intervention was delivered by 3 licensed occupational therapists with experience working with children with ASDs. The primary outcome was Goal Attainment Scaling, a systematic process for identifying goals that are relevant to individuals and their families that has been used for evaluation of patients with autism. 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. A strength of this study is its use of a protocolized intervention and its attempt to use an outcome measure relevant to patients and families. However, further replication in a larger sample of patients and further validation of the Goal Attainment Scaling score process is required.

A pilot study reported in 2011 randomized 37 children with a sensory processing disorder (21 with autism, 16 with pervasive developmental disorder not otherwise specified) to SI interventions or to fine motor interventions (18 treatments over 6 weeks). Fidelity to SI interventions was verified with a fidelity measure developed for research by Parham et al. Blinded evaluation at the conclusion of the intervention found no significant difference between the 2 groups on the Quick Neurological Screening Test (QNST) or sensory
processing scores except for Autistic Mannerisms (eg, stereotyped or self-stimulatory behavior) subscale. The SI group demonstrated greater improvement than the fine motor group on individualized Goal Attainment Scaling scores. Post hoc analysis found that more children in the SI group were able to complete parts of the standardized QNST after the intervention. This finding is limited by the post hoc analysis and the difference in the 2 groups at baseline.

In 2007, members of the Sensory Processing Disorders Scientific Workgroup reported 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 randomly assigned to 1 of 3 groups consisting of occupational therapy with SI (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 by 5 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 this small study.

In a 2003 study of 45 children with Down syndrome divided into 3 treatment groups (SIT alone, vestibular stimulation combined with SIT, neurodevelopmental therapy), Uyanik et al reported greater improvements in outcomes in the vestibular stimulation with SIT group and in the neurodevelopmental therapy group when compared with 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 are limited by small sizes, heterogeneous patient populations, and variable outcome measures. As a result, the evidence is insufficient to draw conclusions about the effects of, and the most appropriate patient populations for, SIT.

**Auditory Integration Therapy**

Although auditory integration therapy has been proposed as a therapy for a number of neurobehavioral disorders, the largest body of evidence on AIT relates to its use in ASD.

A 2011 Cochrane review evaluated auditory integration training along with other sound therapies for ASD. Included were 6 RCTs of AIT and one of Tomatis therapy, comprising a total of 182 subjects aged 3 to 39
years. For most of the studies, the control condition consisted of listening to unmodified music for the same time as the active treatment group. Allocation concealment was inadequate for all studies, and 5 of the trials had fewer than 20 participants. Meta-analysis 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 did not achieve statistical significance. The review found no evidence that AIT is an effective treatment for ASD; however, evidence was not sufficient to prove that it is not effective.

In the 2015 systematic review by Brondino et al (described above) examined complementary and alternative therapies for autism, the authors identify the same 6 RCTs of AIT that were included in the 2011 Cochrane review. Similar to the Cochrane review, Brondino et al concluded that the largest studies did not report an improvement with AIT.

A 2010 systematic review of therapies for autism evaluated the evidence for AIT. The author 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.

In 2009, Rossignol conducted a systematic review of novel and emerging treatments for ASD, including AIT. The authors identified one 3-month, double-blind, controlled study of AIT in 17 individuals with autism, which demonstrated significant improvements 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 et al previously referenced. Overall, the authors concluded that there was grade C evidence related to the use of AIT in autism (at least 1 level 2b [individual prospective, nonrandomized cohort study or low-quality RCT] or 3b studies [systematic review of retrospective case-control studies with homogeneity] or 2 level 4 studies [case series or reports]).

Section Summary: Auditory Integration Therapy
The largest body of evidence related to the use of AIT is in the treatment of autism. 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 multiple RCTs and systematic reviews of these trials. 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 multiple RCTs 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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09/03/2009 Medical Policy Committee review
09/09/2010 Medical Policy Committee review
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
10/08/2015 Medical Policy Committee review
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.
Next Scheduled Review Date: 10/2018

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