HMSA

Specific policy administered by National Imaging Associates, Inc. (NIA)

Clinical guidelines OUTPATIENT HABILITATIVE PHYSICAL AND OCCUPATIONAL THERAPY	
Physical Medicine – Clinical Decision Making	**Original Date:** November 2015
Guideline Number: HMSA_CG_603	**Last Revised Date (by HMSA):** December 2022
	Last Reviewed Date (by NIA): December 2022
	Implementation Date: July 2023

Policy Statement

Habilitative physical and occupational therapy services may or may not be covered by all clients of this organization. If the service is covered, it may or may not require prior authorization. These guidelines apply to all markets and populations, including teletherapy, contracted with this organization through the corresponding state health plans unless a market-specific health plan has been developed. Services may be covered when provided for the end result of achieving age-appropriate growth/development; correcting or improving a physical condition; or helping a patient acquire, maintain, or regain functional skills for successful participation in everyday activities. These services must be provided by a skilled and licensed therapy practitioner and in a manner that is in accordance with accepted standards of practice for discipline-specific therapies. It must also be clinically appropriate in amount, duration and scope to achieve their purpose and considered effective treatment for the current injury, illness or condition.

Habilitative physical and occupational therapy should meet the definitions at the end of this document, be provided in a clinic, office, home, or in an outpatient setting and be ordered by either a primary care practitioner or specialist unless otherwise directed by state law or statute.

National Imaging Associates will review all requests resulting in adverse determinations for Medicaid members for coverage under federal Early and Periodic Screening, Diagnostic and Treatment (EPSDT) guidelines.[1,2]

INDICATIONS

Physical and/or occupational therapy evaluation and treatment services are considered medically necessary when the following criteria are met:

- Have written referral from primary care practitioner or other non-physician practitioner (NPP) if required by state guidelines.
- Physical and occupational therapy initial evaluations and re-evaluations that include patient history such as recent illness, injury, or disability along with diagnosis and date of onset and/or exacerbation of the condition. Prior and current level of function as well as identification of any underlying factors that have impacted current functional performance must also be noted.[3-5]
- Formal testing must be age-appropriate, norm-referenced, standardized, and specific to the therapy provided. Test scores should meet the following criteria to establish presence of a motor or functional delay. Notes should document the following to establish the presence of delays or deficits:
    - The following methods are generally accepted measures that may be considered to support a significant delay:
        - Standardized scores at or below the 10th percentile in at least one subtest area for the patient's age.[6]
        - Standardized scores greater than or equal to 1.5 standard deviations below the mean in at least one subtest area for the patient's age.[1,2,6-10]
        - Functional delays may be established by 25% or greater deficit in age equivalency as indicated by established general guidelines of functional assessments or specific criterion-referenced tests or profiles.[1,2,6-8,11]
- While standardized testing is preferred, scores alone may not be used as the sole criteria for determining a patient's medical need for skilled intervention. Test information must be linked to difficulty with or inability to perform everyday tasks.
- In the absence of standardized testing or when test scores show skills within normal ranges despite functional deficits, the documentation must include detailed clinical observations and objective data to document the degree and severity of the condition, in order to support the medical need for skilled services. A caregiver interview/questionnaire can also support the request.
- Any time standardized testing cannot be completed, the documentation must clearly state the reason formal testing could not be done.
    - If the member's medical or cognitive status does not allow for formal testing, the documentation must clearly state the reason formal testing could not be completed.
    - In the absence of standardized testing or when test scores show skills within normal ranges though functional deficits are present, the report must include detailed clinical observations of current skill sets, parent interview/questionnaire

and/or informal assessment supporting Functional Mobility/ADL (Activities of Daily Living) deficits and the medical need for skilled services. The documentation must clearly state the reason formal testing could not be completed.

- Orthopedic diagnoses not related to functional delay including torticollis and gait deviations such as in-toeing or toe walking should include appropriate tests and measures specific to the deficit and the therapy provided.
- In the case of feeding difficulties, the notes must clearly indicate a functional feeding delay as a result of underlying impairments.
  - This may include gagging/choking, oral motor or upper extremity coordination deficits, or maladaptive behaviors due to a food intolerance/aversion preventing adequate oral intake that contribute to malnutrition or decreased body mass index.
  - Fine motor and/or sensory testing, as well as detailed clinical observations of oral motor skills, should also be included in the documentation if functional feeding delays are a result of these component parts of the overall task.
  - Parent report of limited food choices is not adequate to support the medical need for feeding therapy.
  - There must also be evidence of ongoing progress and a consistent home regimen to facilitate carry-over of target feeding skills; strategies; and education of patient, family, and caregiver.
  - Therapies for picky eaters who can eat and swallow normally meeting growth and developmental milestones, eat at least one food from all major food groups (protein, grains, fruits, etc.) and more than 20 different foods is not medically necessary.

- Re-evaluations must be performed annually at a minimum to show progress, support ongoing delays or functional deficits and medical necessity for continued services. Re-evaluations should include updated formal testing that is age-appropriate, norm-referenced, standardized, and specific to the type of therapy provided (see Record Keeping and Documentation Standards, NIA Clinical Guideline 606-01 for additional information regarding re-evaluation requirements). More frequent objective measures may be needed to show progress and support ongoing delays (see progress note section below).
- Retesting with norm-referenced standardized test tools for re-evaluations must occur yearly and may occur every 180 days. Tests must be age appropriate for the child being tested and providers must use the same testing instrument as used in the initial evaluation. If reuse of the initial testing instrument is not appropriate, i.e., due to change in member status or restricted age range of the testing tool, the provider should explain the reason for the change.
- When skilled services are also being provided by other community service agencies and/or school systems, the notes must show how the requested services are working in

coordination with these agencies and not duplicating services. The extent or lack of these additional services must be indicated in the documentation.

- Measurable short and long-term functional goals should be SMART: specific, measurable, attainable, relevant, and timed. Individualized targeted outcomes that are linked to functional limitations outlined in the most recent evaluation/assessment.[12] These goals should include the date in which the goal was established, as well as the date in which the goal is expected to be met. Goals of intervention should target the functional deficits identified by the skilled therapist during the assessment and promote attainment of age appropriate developmental milestones, functional mobility and/or ADL skills appropriate to the patient's age and circumstances.[13]
    - Although identified as component parts of participation, underlying factors, performance skills, client factors or the environment should not be the targeted outcome of long-term goals.
    - In like manner, underlying factors such as strength, range of motion, or cognition should not be the sole focus of short-term goals.[14] When documenting interventions, an explicit connection must be made to what participation outcome the intervention will target.
- Intervention selections must be evidence-based, chosen to address the targeted goals, and representative of the best practices outlined by the corresponding national organizations.[3,5]
    - The ultimate focus of interventions[15] must be to promote motor learning or relatively permanent differences in motor skill capability that can be transferred and generalized to new learning situations.
- The plan of care must include goals detailing type, amount, duration, and frequency of therapy services required to achieve targeted outcomes. The frequency and duration must also be commensurate with the patient's level of disability, medical and skilled therapy needs as well as accepted standards of practice while reflecting clinical reasoning and current evidence.[16]
- Frequency and duration of skilled services must also be in accordance with the following:
    - Intense frequencies (3x/week or more, for a short duration of 2-6 weeks[17]) will require additional documentation and testing supporting a medical need to achieve an identified new skill or recover function with specific, achievable goals within the requested intensive period.[16] Details on why a higher frequency is more beneficial than a moderate or low frequency must be included. Higher frequencies may be considered when delays are classified as severe as indicated by corresponding testing guidelines used in the evaluation. More intensive frequencies may be necessary in the acute phase; however, progressive decline in frequency is expected within a reasonable time frame.
        - On a case-by-case basis, a high frequency requested for a short-term period (4 weeks or less) which does not meet the above criteria may be considered with all of the following documentation

- Letter of medical need from the prescribing provider documenting the member's rehabilitation potential for achieving the goals identified.
- Therapy summary documenting all of the following:
    - Purpose of the high frequency requested (e.g., close to achieving a milestone)
    - Identification of the functional skill which will be achieved with high frequency therapy
    - Specific measurable goals related to the high frequency requested and the expected date the goal will be achieved.

- Moderate frequency (2x/week) should be consistent with moderate delays as established in the general guidelines of formal assessments used in the evaluation. Therapy provided two times a week may be considered when documentation shows one or more of the following:
    - The member is making very good functional progress toward goals
    - The member is in a critical period to gain new skills or restore function or is at risk of regression.
    - The licensed therapist needs to adjust the member's therapy plan and home program weekly or more often than weekly based on the member's progress and medical needs.
    - The member has complex needs requiring ongoing education of the responsible adult.
- Low frequency (at or less than 1x/week)
    - Therapy provided one time per week or less may be considered when the documentation shows one or more of the following[16]:
        - The member is making progress toward their goals, but the progress has slowed, or documentation shows the member is at risk of deterioration due to the member's medical condition.
        - The licensed therapist is required to adjust the member's therapy plan and home program weekly to every other week based on the member's progress.
        - Every other week therapy is supported for members whose medical condition is stable, they are making progress, and it is anticipated the member will not regress with every other week therapy.
        - Frequencies less than every other week may be appropriate for those children who cannot yet tolerate more frequent therapy sessions. They may also have needs that are addressed on a periodic basic as part of comprehensive management in a specialty clinic. Occasional consultation may be appropriate to ensure gains continue, to address emerging concerns, or to help order equipment and train in its use.

    - All requested frequencies must be supported by skilled treatment interventions regardless of level of severity of delay.[18]
- Documentation should clearly reflect why the skills of a therapist are medically necessary. There must be evidence as to whether the services are considered reasonable, effective treatments requiring the skills of a therapist or whether they can be safely and effectively carried out by non-skilled personnel without the supervision of qualified professionals.
- Clinical updates that include current objective measures, progress towards goals, and requested frequency and duration of care are expected at regular intervals or when additional care is requested. Documentation should include:
    - The patient's current level of function, any conditions that are impacting his/her ability to benefit from skilled intervention.
    - Objective measures of the patient's overall functional progress relative to each treatment goal as well as a comparison to the previous progress report.[19]
        - Outcomes should assist in functional skill acquisition is sustained over time.
    - Skilled treatment techniques that are being utilized in therapy as well as the patient's response to therapy and why there may be a lack thereof.
    - An explanation of any significant changes in the plan of care and clinical rationale for why the ongoing skills of a PT/OT are medically necessary.
    - In the case of maintenance programs, clear documentation of the skilled interventions rendered and objective details of how these interventions are preventing deterioration or making the condition more tolerable must be provided. The notes must also clearly demonstrate that the specialized judgment, knowledge, and skills of a qualified therapist (as opposed to a non-skilled individual) are required for the safe and effective performance of services in a maintenance program.
- Maintenance Level/Prevent Deterioration
    - This frequency level (e.g., every other week, monthly, every 3 months) is used when the therapy plan changes very slowly, the home program is at a level that may be managed by the member or the responsible adult/caregiver, or the therapy plan requires infrequent updates by the skilled therapist.
        - Documentation must show that the habilitative plan of care has ended, and a new plan of care established for maintenance.
    - Goals in the plan of care must be updated to reflect that care is focused on maintaining the current level of functioning and preventing regression, rather than progressing or improving function
    - A maintenance level of therapy services may be considered when a member requires skilled therapy for ongoing periodic assessments and consultations and the member meets one of the following criteria:
        - Progress has slowed or stopped, but documentation supports that ongoing skilled therapy is required to maintain the progress made or prevent deterioration.

    - The submitted documentation shows that the member may be making limited progress toward goals or that goal attainment is extremely slow.
    - Factors are identified that inhibit the member's ability to achieve established goals (e.g., the member cannot participate in therapy sessions due to behavior issues or issues with anxiety).
    - Documentation shows the member and the responsible adult have a continuing need for education, a periodic adjustment of the home program, or regular modification of equipment to meet the member's needs.
    - Clear documentation of the skilled interventions rendered and objective details of how these interventions are preventing deterioration or making the condition more tolerable must be provided. The notes must also clearly demonstrate that the specialized judgment, knowledge, and skills of a qualified therapist (as opposed to a non-skilled individual) are required for the safe and effective performance of services in a maintenance program.
- If the patient is not progressing, then documentation of a revised treatment plan is necessary. Discontinuation of therapy may be considered in one or more of the following situations:
    - Member no longer demonstrates functional impairment or has achieved goals set forth in the treatment plan or plan of care
    - Member has returned to baseline function
    - Member can continue therapy with a home treatment program and deficits no longer require a skilled therapy intervention and, for members who are 20 years of age and younger only, maintain status
    - Member has adapted to impairment with assistive equipment or devices
    - Member is able to perform ADLs with minimal to no assistance from caregiver
    - Member has achieved maximum functional benefit from therapy in progress or will no longer benefit from additional therapy
    - Member is unable to participate in the treatment plan or plan of care due to medical, psychological, or social complications; and responsible adult has had instruction on the home treatment program and the skills of a therapist are not needed to provide or supervise the service
    - Testing shows member no longer has a developmental delay
    - Plateau in response to therapy/lack of progress towards therapy goals
    - Non-compliance due to poor attendance and with member or responsible adult, non-compliance with therapy and home treatment program
    - Member has achieved the maximum therapeutic value of a treatment plan, no additional functional improvement is apparent or expected to occur, and the provision of services for a condition cease to be of therapeutic value.
- It is expected that a discharge plan, with the expected treatment frequency and duration, must be included in the plan of care. The discharge plan must indicate the plan to wean services once the patient has attained their goals, if no measurable

functional improvement has been demonstrated, or if the program can be carried out by caregivers or other non-skilled personnel.

- Development of an age-appropriate home regimen to facilitate carry-over of targeted skills and strategies as well as patient, family, and caregiver education in home exercises and self-monitoring should be evident in the documentation. Indication of compliance of the home regimen should be documented to show maximum benefit of care.
- For patients no longer showing functional improvement, a weaning process of one to two months should occur. If the patient shows signs of regression in function, the need for skilled physical or occupational therapy can be re-evaluated at that time. Periodic episodes of care may be needed over a lifetime to address specific needs or changes in condition resulting in functional decline.[20,21]

BACKGROUND

Definitions

Habilitative Physical or Occupational Therapy

Treatment provided by a state-regulated physical or occupational therapist designed to help a person learn, obtain, maintain, prevent deterioration of or improve age-appropriate skills and functioning for daily living.[4,14] These skills may have never been present, lost, or impaired due to a congenital, genetic, or early acquired condition. There must be measurable improvement and progress towards functional goals within an anticipated timeframe toward a patient's maximum potential. Treatment may also be appropriate in an individual with a progressive disorder when it has the potential to prevent the loss of a functional skill or enhance the adaptation to such functional loss. Ongoing treatment is not appropriate when a steady state of sensorimotor functioning has yielded no measurable functional progress.

Rehabilitative Physical or Occupational Therapy

Treatment provided by a state-regulated physical or occupational therapist designed to help a person recover from an acute injury or exacerbation of a chronic condition that has resulted in a decline in functional performance. The specific impact of injury or exacerbation on the patient's ability to perform in their everyday environment must be supported by appropriate tests and measures in addition to clinical observations. Services must be provided within a reasonable time frame (frequency/duration) to restore lost function or to teach compensatory techniques if full recovery of function is not possible.

Maintenance Program

A program established by a licensed therapist that consists of activities and/or mechanisms that will assist the patient in optimizing or maintaining the progress he or she has made during therapy or to prevent or slow further deteriorations due to a disease or illness.

Medical Necessity

Reasonable or necessary services that require the specific training, skills, and knowledge of a physical or occupational therapist in order to diagnose, correct, or significantly improve/optimize as well as prevent deterioration or development of additional physical and mental health conditions. These services require a complexity of care that can only be safely and effectively performed by or under the general supervision of a skilled therapist. Services shall not be considered reasonable and medically necessary if they can be omitted without adversely affecting the member's condition or the quality of medical care. A service is also not considered a skilled therapy service merely because it is furnished by a therapist or by a therapy assistant under the direct or general supervision, as applicable, of a therapist. If a service can be self-administered or safely and effectively carried out by an unskilled person, without the direct supervision of a therapist, as applicable, then the service cannot be regarded as a skilled therapy service even though a therapist actually rendered the service. Similarly, the unavailability of a competent person to provide a non-skilled service, notwithstanding the importance of the service to the patient, does not make it a skilled service when a therapist renders the service.

Activities of Daily Living (ADLs)

Essential activities oriented toward taking care of one's own body (also referred to as basic and/or personal activities of daily living). Such activities are fundamental to living in a social world as well as enabling basic survival and well-being. Specific examples include bathing/showering, toileting, dressing, swallowing/eating, feeding, functional mobility, personal device care, personal hygiene/grooming, and the functional mobility necessary to perform these activities. The initial evaluation and corresponding plan of care should document baseline impairments as they relate to ADL performance deficits with targeted functional outcomes/goals that are measurable, sustainable, and time-specific. Subsequent plans should clearly document functional progress toward attainment of these goals in perspective to the patient's potential ability as well as skilled interventions used to target functional outcomes.[3,5,22]

Functional Mobility Skills

They are considered necessary activities of daily life such as ambulation, transfers, and fine motor skills. The initial plan of care documents baseline impairments as they relate to functional skills with specific goals developed that are specific, measurable, attainable, relevant and time-based (SMART format). Subsequent plans of care document progress toward attainment of these goals in perspective to the patients' potential ability.

Sensory Integration Disorder

Sensory integration involves perceiving, modulating, organizing, and interpreting internal sensations from within the body as well as external sensations from the surrounding environment to optimize occupational performance and participation. Deficits in sensory integration can pose challenges in performing activities of daily living, in addition to development, learning, playing, working, socializing and exhibiting appropriate behavior. Differences in interpretation of stimuli can impact motor skills and coordination, further

limiting engagement and participation. Sensory processing difficulties can occur across the lifespan. Sensory integrative therapy and evidence-based interventions provide neuroscience-based, cognitive, and/or behavioral approaches that support successful adaptive responses.[23]

Sensory Integration Disorder

***NOTE:** See HMSA Sensory Integration Therapy and Auditory Integration Therapy Policy for specific descriptions and coverage limitations for sensory integration therapy.

POLICY HISTORY

Date	Summary
August 2022	• Modified the standardized testing requirements • Clarified requirements for picky eaters • Added goals should be written in SMART format • Clarified the need for clinical update documentation • Added the section for goals in the Maintenance Level/Prevent Deterioration section • Clarified the formal testing section and added additional references to support the accepted measures of a significant delay • Minor editorial changes
December 2021	• Added "General Information" statement • Added "resulting in adverse determinations" within the EPSDT statement for clarification • Added "if required" for written referral under the Indication for evaluation and treatment section • Added medical or cognitive status exceptions under the Indications for evaluation and treatment section • Added orthopedic diagnosis expectations under the Indication for evaluation and treatment section • Added clarification for re-evaluation and retesting requirements • Added focus of intervention under intervention section • Added clarification of high, moderate, and low frequency under frequency and duration for skilled services section as this was adapted from the Superior Health Plan Policy • Added Maintenance Level/Prevent Deterioration section • Added clarification for Discontinuation of therapy services section
October 2020	• Added indication of home program compliance for max benefit of therapy as part of updated POC

	• Added additional resource which supports episodic care and appropriate frequencies • Added EPSDT language in policy statement section • Added annual tests be performed at a minimum of once a year and formalized progress assessment with updated measures at routine intervals may also be needed prior to the one-year mark from previous testing. • Removed "physician-prescribed" from the medical necessity definition in the background • Added qualifier for proof of skilled treatment for requested frequencies regardless of level of severity of delay • Added clarification on need for documentation to support ongoing requested frequencies with showing effective outcomes and reasonable time frames • Added clarification for when test scores are within normal, yet functional delays are present • Added teletherapy to the policy statement
January 2020	• No content changes following review of the evidence base. Minor copyediting changes.
July 2019	• Definitions were moved to the background so pertinent information was readily available at the beginning of the document. • Existing definitions were revised to include greater detail with new definitions for *rehabilitative therapy* (for comparative purposes), *medical necessity* and *maintenance program* included. • Criteria for delay was revised to include clearer and more detailed specifications for functional delays, preferred scoring, and what is required in the absence of standardized testing. • Criteria for feeding delays were added. • Additional specifications included for linking testing to the treatment goals, inclusion of functional treatment goals, utilizing appropriate dosing of therapy and specifying skilled interventions.

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ADDITIONAL RESOURCES

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Reviewed/Approved by NIA Clinical Guideline Committee

GENERAL INFORMATION

It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.

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Sensory Integration Therapy and Auditory Integration Therapy

Policy Number: MM.09.007	**Current Effective Date:** April 22, 2022
Lines of Business: HMO; PPO; QUEST Integration	**Original Effective Date:** May 01, 2015
Place of Service: Outpatient	**Precertification:** Not Required

I. Description

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.

For individuals who have developmental disorders who receive SIT, the evidence includes randomized controlled trials, systematic reviews of these trials, and case series. The 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 randomized controlled trials are needed to evaluate the efficacy of this intervention. The most direct evidence on SIT outcomes derives from several randomized trials (RCTs). 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 that the technology results in an improvement in the net health outcome.

For individuals who have developmental disorders who receive AIT, the evidence includes several randomized controlled trials and systematic reviews of these trials. The 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 that the technology results in an improvement in the net health outcome.

II. Policy Criteria

Sensory integration therapy and auditory integration therapy are not covered because they are not known to be effective in improving health outcomes.

III. Administrative Guidelines

A. The provider cannot bill or collect charges for these services unless a written acknowledgement of financial responsibility, specific to the service, is obtained from the Member prior to the time services are rendered.

B. Patients requesting services that are not covered should be informed that they will be responsible to pay for the services. To prevent misunderstandings about financial

responsibility, the provider may ask the patient to sign an Acknowledgement of Financial Responsibility prior to performing the services.

C. Applicable codes

CPT Code	Description
97533	Sensory integrative techniques to enhance sensory processing and promote adaptive responses to environmental demands, direct (one-on-one) patient contact, each 15 minutes
ICD-10-CM Code	**Description**
F84.0-F84.9	Pervasive developmental disorders code range (includes infantile autism, etc.)

IV. Scientific Background

The goal of sensory integration therapy (SIT) 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.

Regulatory Status

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.

Rationale

This evidence review was created in April 2000 and has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through January 19, 2022.

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, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 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 PICO was used to select literature to inform this review.

Populations

The relevant population of interest is 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 quality of life (QOL). Follow-up of at least six months would be desirable to assess outcomes.

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 sensory integration therapy"

- "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.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews

Several systematic reviews have addressed the use of SIT in various clinical conditions (Tables 1 and 2). Four of the 5 systematic reviews included in this evidence review pertain to studies evaluating SIT for autism spectrum disorder (ASD), while 1 included studies in individuals with a broader range of developmental disabilities.

Table 1. Comparison of Studies Included in Systematic Reviews of Sensory Integration Therapy

Randomized Controlled Trials (RCTs)	Weitlauf et al (2017)	Case-Smith et al (2015)	Brondino et al (2015)	Watling and Hauer (2015)	May-Benson et al (2010)
Carte et al (1984)					●
Fazlioğlu et al (2008)	●	●	●	●	
Grimwood et al (1980)					●
Humphries et al (1990)					●
Humphries et al (1992)					●
Humphries et al (1993)					●
Iwanaga et al (2014)	●				
Miller et al (2007)					●
Morrison et al 1986)					●
Pfeiffer et al (2011)	●	●	●	●	
Piravej et al 2009)				●	
Polatajko et al (1991)					●
Reilly et al (1983)			●		
Schaaf et al (2013)	●	●		●	
Werry et al (1990)					●
White (1979)					●
Wilson et al (1992)					●
Wilson et al (1994)					●
Woo et al (2013)				●	
Ziviani et al (1982)					●

Other Case Study Designs

	Weitlauf et al (2017)	Case-Smith et al (2015)	Brondino et al (2015)	Watling and Hauer (2015)	May-Benson et al (2010)
Allen et al (1995)					●
Ayres (1972)					●
Ayres (1977)					●
Bagatell et al (2010)		●		●	
Bullock et al (1978)					●
Bundy et al (2007)					●
Candler et al (2003)					●
Case-Smith et al (1999)					●
Cox et al (2009)		●		●	
Davis et al (2011)		●			
Devlin et al (2009)		●			
Devlin et al (2011)		●		●	
Fertel-Daly (2001)		●			
Hodgetts et al (2010)		●			
Hodgetts et al (2011)		●		●	
Kane et al (2004)		●			
Kinnealey et al (2012)				●	
Leemrijse et al (2000)					●
Leew et al (2010)		●		●	
Linderman et al (1999)					●
Miller et al (2007)					●
Ottenbacher et al (1979)					●
Ottenbacher et al (1982)					●
Quigley et al (2011)				●	
Reichow et al (2010)		●		●	
Roberts et al (2007)					●
Schaaf et al (2012)		●			
Schilling et al (2004)		●			
Schroeder et al (1982)					●
Smith et al (2005)		●			
Thompson et al 2011			●	●	
Umeda et al (2011)				●	
Van Rie et al (2009)		●			
Watling et al (2007)				●	
Watling et al (2010)		●			
Wuang et al (2010)				●	

Table 2. Characteristics of Systematic Reviews of Sensory Integration Therapy

Study	Search Dates	Studies	Populations
Brondino et al (2015)	Through Oct 2014	3 RCTs, 1 other design	ASD
Case-Smith et al (2015)	2000 - 2012	2 RCTs, 3 other design	ASD
May-Benson et al (2010)	1972-2007	13 RCT, 14 other designs	Children with difficulty processing and integrating sensory information
Watling and Hauer (2015)	2006 - 2013	5 RCTs, 15 other design	ASD
Weitlauf et al (2017)	2010-2016	3 RCT, 1 other design	ASD

ASD: autism spectrum disorder; RCT: randomized controlled trial

In a systematic review conducted for the Agency for Healthcare Research and Quality (AHRQ), Weitlauf et al (2017) evaluated the effectiveness and safety of a variety of interventions targeting

sensory challenges in ASD. The reviewers included 3 RCTs and 1 retrospective cohort study of sensory-integration-based approaches, defined as interventions using combinations of sensory and kinetic components, such as materials with different textures, touch/massage, swinging and trampoline exercises, and balance and muscle resistance exercises. One study was rated low risk of bias, 1 moderate, and 2 high risk of bias. Significant heterogeneity across studies in interventions and outcome measures precluded meta-analysis. In 3 of 4 studies, sensory-related measures and motor skills measures improved for children receiving the sensory-integration based intervention, however the strength of this evidence was rated low due to small sample sizes and short study durations. The studies were also limited by a lack of blinding when parent-reported outcome measures were used. The reviewers concluded, "Although some therapies may hold promise and warrant additional study, substantial needs exist for continuing improvements in methodologic rigor in the field."

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, 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. Findings from one RCT included significant improvement in individualized goals, improved sleep, decreased ASD mannerisms, and reduced caregiver burden. The reviewers concluded that there

was moderate strength evidence to support the use of Ayres Sensory Integration and mixed results for sensory-based methods. They recommended additional, higher-level studies with larger sample sizes and using standardized definitions of interventions and outcome measures.

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.

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
Clinical Context and Purpose
The purpose of Auditory Integration Therapy (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 PICO was used to select literature to inform this review.

Populations
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. Auditory integration therapy 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.

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.

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

Study Selection Criteria
Methodologically credible studies were selected using the principles described in the first indication.

Review of Evidence
Systematic Reviews
In their systematic review of sensory interventions conducted for AHRQ, Weitlauf et al (2017) included 4 RCTs of auditory integration therapy. Two small, short-term RCTs with moderate risk of bias reported no significant differences between auditory integration and control groups in language outcomes assessed on parent, teacher, and clinician observation measures. Two other RCTs, reported in a single publication, reported some parent-rated improvement in hearing sensitivity, spontaneous speech, listening, and behavioral organization, but no difference in other behavioral domains rated. Overall, the reviewers concluded that there is low strength evidence that auditory integration-based approaches do not improve language outcomes.

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; described above) 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.

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. 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 that the technology results in an improvement in the net health outcome.

For individuals who have developmental disorders who receive AIT, the evidence includes several RCTs and systematic reviews of these trials. 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 that the technology results in an improvement in the net health outcome.

V. 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

American Academy of Pediatrics

A 2012 policy statement by the American Academy of Pediatrics on SIT for children with developmental and behavioral disorders stated that "occupational 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 American Academy of Pediatrics 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 2015 American Occupational Therapy Association (AOTA) guidelines stated: "American Occupational Therapy Association (AOTA) recognizes 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 "enhanc[e] a person's ability to participate in life through engagement in everyday activities…When children demonstrate sensory, motor, or praxis defects that interfere with their ability to access the general education curriculum, occupational therapy using an sensory integration approach is appropriate".

In 2011, the American Occupation Therapy Association (AOTA) 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).

American Speech-Language-Hearing Association
In 2002, the American Speech-Language-Hearing Association Work Group on Auditory Integration Therapy concluded that auditory integration therapy has not met scientific standards for efficacy that would justify its practice by audiologists and speech-language pathologists.

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 3.

Table 3. Summary of Key Trials

NCT/ISRCTN Number	Trial Name	Planned Enrollment	Completion Date	Status
ISRCTN14716440	A Trial of Sensory Integration Therapy Versus Usual Care for Sensory Processing Difficulties in Autism Spectrum Disorder in Children	138	Sept 2020 (last updated Feb 2021)	Unpublished
NCT02536365	Sensory Integration Therapy in Autism: Mechanisms and Effectiveness	180	Dec 2021	Unpublished
NCT04696133	Therapeutic Outcomes of Sensory Integration Versus Fine Motor Intervention in Children with Autism	30	Dec 2021	Unpublished

ISRCTN: International Standard Randomized Controlled Trial Number; NCT: national clinical trial.

VI. Important Reminder

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii's Patients' Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), or for QUEST members, under Hawaii Administrative Rules (HAR 1700.1-42), generally accepted standards of medical practice and review of medical literature and government approval status.

HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA's determination as to medical necessity in a given case, the physician may request that HMSA

reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

VII. References

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17. BlueCross BlueShield Association. Sensory Integration Therapy and Auditory Integration Therapy. Medical Policy Reference Manual. Policy 8.03.13. Revised April 2022.

VIII. Policy History

Action Date	Action
December 11, 2014	Policy reviewed by Medical Director, Larry Burgess, M.D.
December 16, 2014	Policy approved by Medical Directors
December 19, 2014	Policy approved by UMC
May 1, 2015	Effective after 90 days' notice
November 23, 2016	Policy reviewed by Medical Director, Larry Burgess, M.D.
December 20, 2016	Policy approved by Medical Directors
December 30, 2016	Policy approved by UMC
March 15, 2017	Policy reviewed by Medical Director, Larry Burgess, M.D.
April 4, 2017	Policy approved by Medical Directors
April 28, 2017	Policy approved by UMC
April 17, 2018	Policy reviewed by Medical Director, Larry Burgess, M.D.
May 01, 2018	Policy approved by Medical Directors
May 25, 2018	Policy approved by UMC
April 29, 2019	Policy reviewed by Medical Director, Larry Burgess, M.D.
May 07, 2019	Policy approved by Medical Directors
May 24, 2019	Policy approved by UMC
April 28, 2020	Policy reviewed by Medical Director, Larry Burgess, M.D.
May 5, 2020	Policy approved by Medical Directors
May 22, 2020	Policy approved by UMC
April 13, 2021	Policy reviewed by Medical Director, Larry Burgess, M.D.
April 20, 2021	Policy approved by Medical Directors
April 23, 2021	Policy approved by UMC
March 30, 2022	Policy reviewed by Medical Director, Larry Burgess, M.D.
April 5, 2022	Policy approved by Medical Directors
April 22, 2022	Policy approved by UMC
August 1, 2022	Policy revised to meet WCAG compliance; Expired links removed or updated

IX. Signatures

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Chair of Utilization Management Committee Date

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HMSA QUEST Integration Medical Director Date