



PROVIDER POLICIES & PROCEDURES

ORTHOPEDIC AND DIABETIC SHOES

The primary purpose of this document is to assist providers enrolled in the Connecticut Medical Assistance Program (CMAP Providers) with the information needed to support a medical necessity determination for orthopedic and diabetic shoes. By clarifying the information needed for prior authorization of services, HUSKY Health hopes to facilitate timely review of requests so that individuals obtain the medically necessary care they need as quickly as possible.

Orthopedic shoes, shoe modifications, or shoe additions are used in the treatment of children, to correct, accommodate or prevent a physical deformity or range of motion malfunction in a diseased or injured part of the ankle or foot; in the treatment of children, to support a weak or deformed structure of the ankle or foot; as a component of a comprehensive orthopedic treatment plan to treat various conditions of the foot; or to form an integral part of an orthotic brace. In order to qualify as orthopedic footwear, the footwear must be made and marketed by the manufacturer as “orthopedic” footwear and aim to prevent or correct foot deformity.

Diabetic shoes are designed to reduce the likelihood of blisters, sores and chaffing occurring by creating an environment within the shoe that has sufficient room for movement, while inhibiting pressure and abrasive points. Foot ulcerations, infection, peripheral neuropathy, and lower extremity amputations are some of the common consequences of diabetes. Effective management, including therapeutic “diabetic” shoes, inserts or modifications may assist in the prevention of or delay of adverse outcomes.

CLINICAL GUIDELINE

Coverage guidelines for orthopedic and diabetic shoes will be made in accordance with the DSS definition of Medical Necessity. The following criteria are guidelines *only*. Coverage determinations are based on an assessment of the individual and his or her unique clinical needs. If the guidelines conflict with the definition of Medical Necessity, the definition of Medical Necessity shall prevail. The guidelines are as follows:

Orthopedic and diabetic shoes are typically limited to two (2) pairs per calendar year for those individuals 21 years of age and over. Exceptions to this limit require a prior authorization. Prior authorization is not required for shoe modifications or additions.

Orthopedic shoes

An additional pair of orthopedic shoes is typically considered medically necessary when the individual has an orthopedic deformity and there is evidence of a significant change in the individual’s orthopedic condition, or other circumstance, since receiving the existing two pair of orthopedic shoes.

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A custom-molded shoe is typically considered medically necessary when the individual has an orthopedic foot deformity that cannot be accommodated by an extra-depth shoe.

Replacement of orthopedic shoes is typically considered medically necessary when an anatomical change or reasonable wear and tear renders the item nonfunctional and/or non-repairable, including documented measurable evidence that the individual has one or more of the following:

- a. Measurable/objective evidence of a significant change or worsening of a foot deformity;
- b. Evidence of excessive wear on current shoes; or
- c. Growth in foot/feet size greater than ½", associated with a leg length discrepancy or structural foot deformity.

Sneakers, high-top shoes/boots, and athletic shoes are typically *not considered* orthopedic shoes and therefore not medically necessary. However, these items may be considered medically necessary based on an assessment of the individual and his or her unique clinical needs.

Diabetic Shoes

An additional pair of diabetic shoes is typically considered medically necessary when:

1. The individual has a diagnosis of diabetes mellitus and there is evidence of a significant change in the individual's medical condition since receiving the existing two pair of diabetic shoes; and
2. The individual has one or more foot complications as a result of diabetes.

Deluxe features such as special or additional shoe colors, special leathers, and styles do not contribute to the accommodative or therapeutic function of orthopedic and diabetic shoes and are therefore *not* considered medically necessary. However, these features may be considered medically necessary in certain instances based on an assessment of the individual and his or her unique clinical needs.

NOTE: EPSDT Special Provision

Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) is a federal Medicaid requirement that requires the Connecticut Medical Assistance Program (CMAP) to cover services, products, or procedures for Medicaid enrollees under 21 years of age where the service or good is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition identified through a screening examination. The applicable definition of medical necessity is set forth in Conn. Gen. Stat. Section 17b-259b (2011) [ref. CMAP Provider Bulletin PB 2011-36].

PROCEDURE

Prior authorization of orthopedic and diabetic shoes, beyond the two (2) pair per year limit is required. Requests for coverage will be reviewed in accordance with the procedures in place for reviewing requests for DME. Coverage determinations will be based upon a review of submitted case-specific information.

Prior to supplying orthopedic or diabetic shoes, the medical equipment, device and supplies provider should review the individual's claim history via the Department of Social Services (DSS) web portal. The claim history inquiry feature on the web portal verifies if the individual has met the benefit limit of two (2) pairs of orthopedic and diabetic shoes per calendar year indicating whether a prior authorization is required.

Prior authorization is not required for shoe modifications or additions.

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The following information is needed to review requests for orthopedic shoes:

1. Fully completed Outpatient Prior Authorization Request Form or fully completed authorization request via on-line web portal;
2. A copy of a recent foot exam, biomechanical exam or gait analysis performed by the individual's physician;
3. Documentation from the individual's physician demonstrating an objective and measurable change in the individual's orthopedic condition, or other circumstance, since receiving the previous pair of orthopedic shoes. An objective and measurable change is determined by comparing the individual's status at the time of dispensing or evaluating the individual's current shoes to the individual's present status;
4. Explanation why commercially available off-the-shelf shoes will not address the person's orthopedic needs;
5. Physician prescription including a description of additions or modifications; e.g., padding or offloading type and location, rocker soles, indicating the reason why an additional pair of orthopedic shoes is needed within the calendar year; and
6. The manufacturer, style, and size for both the current pair (when available) and requested pair of orthopedic shoes.

The following information is needed to review requests for diabetic shoes:

1. Fully completed Outpatient Prior Authorization Request Form or fully completed authorization request via on-line web portal;
2. Documentation from the individual's physician supporting a change in the individual's condition since receiving the previous pair of diabetic shoes. An objective and measurable change is determined by comparing the individual's status at the time of dispensing or evaluating the individual's current shoes to the individual's present status;
3. Documentation from the individual's physician, managing the diabetic condition, certifying that the indications above are met, that he/she is treating the individual under a comprehensive plan of care, and that the individual's medical needs have changed necessitating additional diabetic shoes during the current calendar year; and
4. Physician prescription including a description of additions or modifications; e.g., padding or offloading type and location, specialized shoe materials, foam inserts, indicating the reason why an additional pair of orthopedic shoes is needed within the calendar year.

Note:

- DSS may conduct post-payment auditing of orthopedic and diabetic shoe claims.
- Funds received for orthopedic and/or diabetic shoes beyond the two pair per calendar year limit, that were not prior authorized, will be recovered from the billing provider.

EFFECTIVE DATE

This policy is effective for prior authorization requests for orthopedic and diabetic shoes for individuals covered under the HUSKY Health Program on or after March 1, 2013.

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LIMITATIONS

Orthopedic and diabetic shoes are not covered for individuals enrolled in the HUSKY B Program. Individuals enrolled in the HUSKY B program may be eligible for these items under the HUSKY Plus Program. HUSKY Plus provides supplemental coverage of children with intensive physical health needs for services not covered under the HUSKY B plan. Call 1-800-440-5071 for more information.

CODES:

Code	Description
A5500	For diabetics only, fitting (including f/u), custom preparation and supply of off- the-shelf depth-inlay shoe manufactured to accommodate multi-density insert(s), per shoe.
A5501	For diabetics only, fitting (including f/u), custom preparation and supply of shoe molded from cast(s) of patients foot (custom molded shoe) per shoe.
L3201	Orthopedic shoe, Oxford with supinator or pronator, infant
L3202	Orthopedic shoe, Oxford with supinator or pronator, child
L3203	Orthopedic shoe, Oxford with supinator or pronator, junior
L3204	Orthopedic shoe, High-top with supinator or pronator, infant
L3206	Orthopedic shoe, High-top with supinator or pronator, child
L3207	Orthopedic shoe, High-top with supinator or pronator, junior
L3215	Orthopedic footwear, ladies shoe, oxford, each.
L3216	Orthopedic footwear, ladies shoe, depth inlay, each.
L3217	Orthopedic footwear, ladies shoe, high-top, depth inlay, each.
L3219	Orthopedic footwear, men's shoe, oxford, each.
L3221	Orthopedic footwear, men's shoe, depth inlay, each.
L3222	Orthopedic footwear, men's shoe, high-top, depth inlay, each.
L3224	Orthopedic footwear, women's shoe, oxford, used as an integral part of a brace (orthotic).
L3225	Orthopedic footwear man's shoe, oxford, used as an integral part of a brace (orthotic).
L3230	Orthopedic footwear, custom shoe, depth inlay, each.
L3250	Orthopedic footwear, custom molded shoe, removable inner mold, prosthetic shoe, each.
L3251	Foot, shoe molded to patient model, silicone shoe, each.
L3252	Foot, shoe molded to patient model, Plastazote (or similar) custom fabricated, each.
L3253	Foot, molded shoe, Plastazote (or similar) custom fitted, each.
L3265	Plastazote sandal, each.

DEFINITIONS

1. **Diabetes:** a chronic illness in which the body does not properly produce or use insulin.
2. **Diabetic shoes:** shoes designed to reduce the likelihood of blisters, sores and chaffing occurring by creating an environment within the shoe that has sufficient room for movement, while inhibiting pressure and abrasive points. Typical features of good diabetic shoes include:
 - roomy toe boxes without lining stitching or seams that can cause abrasions, and

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- thick, cushioned and contoured in-soles, often featuring extra levels of padding, particularly around the balls of the feet and the heel area at high risk, and
 - smooth, seamless linings without projections or rubbing areas that could cause blisters or sores, and
 - incorporation of good ventilation, both through the shoes design and use of materials, and
 - comfort fit design that allow a level of elasticity, especially around the upper surface of the foot to allow the foot to expand and avoid pressure points, and
 - simple adjustment for tightening, loosening or changing in-soles.
3. **Foot Deformities:** Foot deformities such as flatfoot (pes planus) and bunions (hallux valgus) may cause malalignment of the feet and/or ankles and pathologic foot positioning, thereby causing impaired gait, balance and pain. Flatfoot deformity may occur in both pediatric and adult populations. The degree of flatfoot is subjective, and treatment decisions are usually based on the presence or absence of pain, Achilles contracture, or accessory navicular (Jackson and Stricker, 2003). It has been proposed that orthotic devices can relieve symptoms by providing structural support to the weakened foot, by limiting the amount of abnormal pronation, or by allowing more efficient locomotion (Noble, 2001). The American College of Foot and Ankle Surgeons (ACFAS) Clinical Practice Guidelines (Lee et al., 2004; Harris et al., 2004; Vanore et al., 2003) describe the following:
 4. **Foot Orthotics:** Shoe inserts that are intended to correct foot function and minimize stress forces that could ultimately cause foot deformity and pain by altering slightly the angles at which foot strikes a walking or running surface.
 5. **HUSKY A:** Connecticut children and their parents or a relative caregiver; and pregnant women may qualify for HUSKY A (also known as Medicaid). Income limits apply.
 6. **HUSKY B:** Uninsured children under the age of 19 in higher income households may be eligible for HUSKY B (also known as the Children’s Health Insurance Program) depending on their family income level. Family cost-sharing may apply.
 7. **HUSKY C:** Connecticut residents who are age 65 or older or residents who are ages 18-64 and who are blind, or have another disability, may qualify for Medicaid coverage under HUSKY C (this includes Medicaid for Employees with Disabilities (MED-Connect), if working). Income and asset limits apply.
 8. **HUSKY D:** Connecticut residents who are ages 19-64 without dependent children and who: (1) do not qualify for HUSKY A; (2) do not receive Medicare; and (3) are not pregnant, may qualify for HUSKY D (also known as Medicaid for the Lowest-Income populations).
 9. **HUSKY Health Program:** The HUSKY A, HUSKY B, HUSKY C, HUSKY D and HUSKY Limited Benefit programs, collectively.
 10. **HUSKY Limited Benefit Program or HUSKY, LBP:** Connecticut’s implementation of limited health insurance coverage under Medicaid for individuals with tuberculosis or for family planning purposes and such coverage is substantially less than the full Medicaid coverage.
 11. **Medically Necessary or Medical Necessity:** (as defined in Connecticut General Statutes § 17b-259b) Those health services required to prevent, identify, diagnose, treat, rehabilitate or ameliorate an individual's medical condition, including mental illness, or its effects, in order to attain or maintain the individual's achievable health and independent functioning provided such services are: (1) Consistent with generally-accepted standards of medical practice that are defined as standards that are based on (A) credible scientific evidence published in peer-reviewed medical literature that is generally recognized by the relevant medical community, (B) recommendations of a physician-specialty society, (C) the views of physicians practicing in relevant clinical areas, and (D) any other relevant factors; (2) clinically appropriate in terms of type, frequency, timing, site, extent and duration and considered effective for the individual's illness, injury or disease; (3) not primarily for the convenience of the individual, the individual's health care provider or other health care providers; (4)

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not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the individual's illness, injury or disease; and (5) based on an assessment of the individual and his or her medical condition.

12. **Metatarsal bars:** Exterior bars that are placed behind the metatarsal heads in order to remove pressure from the metatarsal heads. The bars are of various shapes, heights, and construction depending on the exact purpose.
13. **Offset heel:** A heel flanged at its base either in the middle, to the side, or a combination, that is then extended upward to the shoe in order to stabilize extreme positions of the hind foot.
14. **Orthopedic shoes, shoe modifications, or shoe additions:** Orthopedic shoes, shoe modifications or shoe additions are used as follows: in the treatment of children, to correct, accommodate or prevent a physical deformity or range of motion malfunction in a diseased or injured part of the ankle or foot; in the treatment of children, to support a weak or deformed structure of the ankle or foot; as a component of a comprehensive orthopedic treatment plan to treat amputation, ulceration, pre-ulcerative calluses, peripheral neuropathy with evidence of callus formation, a foot deformity or poor circulation; or to form an integral part of an orthotic brace. Although there is not definition of an orthopedic shoe, this type of footwear is designed to accommodate specific foot deformities. In order to qualify as orthopedic footwear, the footwear must be made and marketed by the manufacturer as "orthopedic" footwear and aim to prevent or correct foot deformity and must meet the following specifications:
 - Blucher or Bal construction,
 - Leather construction or synthetic material of equal quality,
 - Welt construction with a cement attached outsole or sewn on outsole,
 - Upper portion properly fitted as to length and width,
 - No unit sole,
 - Bottom sized to the last,
 - Closure appropriate to foot condition (Velcro strap or lace closure preferred),
 - Full range of width, not just narrow, medium, wide;
 - Extended medial counter and firm heel counter.

In addition, orthopedic footwear typically includes the following options:

- Size selection that includes not only a standard shoe size fitting, but also separate size classifications for *insole width* and sometimes a further sizing for the toe *box width* (or toe girth) at the front of the shoe.
- A removable insole contoured to the shape of a healthy foot with adequate cushioning to absorb walking impact and provide comfort when walking, standing or sitting. This insole should be removable, replaceable and washable. Some orthopedic shoes offer insoles made from visco elastic memory foam or gel.
- Breathable uppers that allow air circulation and prevent the feet from becoming hot and the shoe from becoming damp. There should be adequate depth to, and the around, the areas known as the vamp "upper" and the vamp "lower" to the front of the shoe.
- Easy fit fastenings that include *hook and loop* (Velcro) type methods of securing the shoe rather than shoe laces (which can provide pressure points and uneven support around the shoe tongue).
- The lining should be seamless with no projections or areas capable of causing rubbing or abrasion.
- The heel collar and heel counter that supports the back of the foot (the heel) should be firm and supportive and difficult to bend or compress by hand.

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- The outer sole, any mid sole, and any *flex* areas should be strong and well cushioned to absorb the rigors of impact resulting from walking. However, they should still be able to flex and be sufficiently tactile to pass on information about the walking surface to enable the foot to react to changing ground features and surface finishes.
- The outer sole should not be overly wedged (i.e. with a high heel) as this will prevent the natural bio mechanics of the foot from working in a healthy way.

Modifications of depth or custom-molded shoes include but are not limited to:

- rigid rocker bottoms roller bottoms
- wedges
- metatarsal bars
- offset heels
- flared heels

A custom-molded shoe is a shoe which:

- is constructed over a positive model of the individual's foot, and
- is made from leather or other suitable material of equal quality, and
- has removable inserts that can be altered or replaced as the individual's condition warrants, and
- has some form of shoe closure.

A high or extra depth shoe is a shoe that:

- has a full length, heel-to-toe filler that, when removed, provides a minimum of 3/16 inch of additional depth used to accommodate custom-molded or customized inserts, and
- is made from leather or other suitable material of equal quality, and
- has some form of shoe closure, and is available in full and half sizes with a minimum of three widths so that the sole is graded to the size and width of the upper portions of the shoe according to the American standard

15. **Peripheral Neuropathy:** A degenerative condition of the nervous system involving the skin of the extremities
16. **Prior Authorization:** A process for approving covered services prior to the delivery of the service or initiation of the plan of care based on a determination by CHNCT as to whether the requested service is medically necessary.
17. **Rigid rocker bottoms:** Exterior elevations with apex position for 51% to 75% distance measured from the back end of the heel. The apex is a narrowed or pointed end of an anatomical structure. The apex must be positioned behind the metatarsal heads and taper off sharply to the front tip of the sole. Apex height helps to eliminate pressure at the metatarsal heads. Rigidity is ensured by the steel in the shoe. The heel of the shoe tapers off in the back in order to cause the heel to strike in the middle of the heel.
18. **Roller bottoms (sole or bar):** The same as rocker bottoms except the heel is tapered from the apex to the front tip of the sole.
19. **Therapeutic shoe insert for diabetics** A total contact, multiple density, prefabricated, removable inlay that is directly molded to the individual's foot or a model of the individual's foot and that is made of a suitable material with regard to the individual's condition. The material responsible for maintaining the shape of the device is called the base layer and must be heat moldable. This material usually constitutes the bottom layer of the device and must be of a sufficient thickness and durometer to maintain its shape during use (e.g., at least ¼ inch of Shore A 35 or higher, or 3/16 inch of Shore A

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40 or higher). Modifications such as additional arch fill may be necessary to achieve and maintain total contact.

20. **Therapeutic shoe insert for diabetics** A total contact, custom fabricated, multiple density removable inlay that is molded to a model of the individual's foot or a model of the individual's foot so and that is made of a suitable material with regard to the individual's condition. A custom fabricated device is made from materials that do not have predefined trim lines for heel cup height, arch height and length or toe shape. The base layer of the device must be of a sufficient thickness and durometer to maintain its shape during use (e.g., at least 3/16 inch of Shore A 35 material or higher). The base layer is allowed to be thinner in the custom fabricated device because appropriate arch fill or other additional material will be layered up individually to maintain shape and achieve total contact. The central portion of the base layer of the heel may be thinner (but at least 1/16 inch) to allow for greater pressure reduction. The specified thickness of the lateral portions of the base layer must extend from the heel through the distal metatarsals and may be absent at the toes. The top layer of the device may be of a lower durometer and must also be heat moldable.

ADDITIONAL RESOURCES AND REFERENCES:

- American Diabetes Association. Available at: <http://www.diabetes.org/>. Accessed on January 24, 2013.
- American Diabetes Association. Standards of medical care in diabetes--2008. Diabetes Care. 2008; Supplement 1:S12-S54
- Centers for Medicare and Medicaid Services (CMS), Health Care Procedural Coding System Level II Manual: 2017
- Centers for Medicare and Medicaid Services (CMS). National Coverage Determination: Durable medical equipment reference list. NCD #280.1. 05/05/2005. Available at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?list_type=ncd. Accessed on January 24, 2013.
- CGS Administrators, LLC. Jurisdiction C. Local Coverage Determination for Orthopedic Footwear (L11445). Revised 03/02/2012. Available at: http://www.cms.hhs.gov/mcd/index_local_alpha.asp?from2=index_local_alpha.asp&from=alphalmr p&letter=A&. Accessed on January 24, 2013.
- Jackson JF, Stricker SJ. Pediatric foot notes: A review of common congenital foot deformities. International Pediatrics. 2003;18(3):133-140. Accessed on January 25, 2013 http://www.irdpq.qc.ca/communication/publications/PDF/Part_4_Specific.pdf in Normative Reference Values for Musculoskeletal Conditions and Functional Motor Abilities in the Pediatric Population, Part 4, Specific Tests.
- Lee MS, Vanore JV, Thomas JL, Catanzariti AR, Kogler G, Kravitz SR, Miller SJ, Gassen SC; Clinical Practice Guideline Adult Flatfoot Panel. Diagnosis and Treatment of Adult Flatfoot. Clinical Practice Guideline. American College of Foot and Ankle Surgeons. Journal of Foot and Ankle Surgery. March/April 2005; 44(2):78-113. Accessed on January 25, 2013 http://www.unboundmedicine.com/medline/citation/15768358/Diagnosis_and_treatment_of_adult_flatfoot
- Medicare Benefit Policy Manual (IOM 100-02). Therapeutic Shoes for Individuals with Diabetes. Chapter 15, Section 140. Rev. 1, 10-01-03. Available at: <http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf>. Accessed on January 24, 2013.

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- National Government Services, Inc. Jurisdiction B. Local Coverage Determination for Orthopedic Footwear (L27220). Revised 03/09/2012. Available at: http://www.cms.hhs.gov/mcd/index_local_alpha.asp?from2=index_local_alpha.asp&from=alphalmr p&letter=A&. Accessed on January 24, 2013.
- NIHC Corp. Jurisdiction A. Local Coverage Determination for Orthopedic Footwear (L11467). Revised 03/05/2012. Available at: http://www.cms.hhs.gov/mcd/index_local_alpha.asp?from2=index_local_alpha.asp&from=alphalmr p&letter=A&. Accessed on January 24, 2013.
- Noridian Administrative Services. Jurisdiction D. Local Coverage Determination for Orthopedic Footwear (L11456). Revised 03/08/2012. Available at: http://www.cms.hhs.gov/mcd/index_local_alpha.asp?from2=index_local_alpha.asp&from=alphalmr p&letter=A&. Accessed on January 24, 2013.
- Spencer S. Pressure relieving interventions for preventing and treating diabetic foot ulcers. Cochrane Database Syst Rev. 2000; (3):CD002302.

PUBLICATION HISTORY

Status	Date	Action Taken
Original publication	January 2013	
Reviewed	December 2013	Clinical Quality Sub-Committee Review. Reference updated. These changes approved at the December 16, 2013 Clinical Quality Sub-Committee meeting.
Updated	April 2014	Deleted diabetic shoe modification codes from policy at request of Department of Social Services (DSS). Changes approved by DSS on April 7, 2014.
Reviewed	December 2014	Clinical Quality Sub-Committee Review. Reference updated. These changes approved at the December 15, 2014 Clinical Quality Sub-Committee meeting.
Updated	August 2015	Updated definitions for HUSKY A, B, C and D programs at request of DSS
Updated	March 2016	Updates to language in introductory paragraph pertaining to purpose of policy. Updates to Clinical Guideline and Information Required for Review sections pertaining to definition of Medical Necessity and documentation requirements. Updates throughout policy to reflect importance of person-centeredness when reviewing requests for these items. Changes approved at the March 21, 2016 Clinical Quality Subcommittee. Removed listing of specific medical conditions from introductory section and Clinical Guideline for Diabetic Shoes section at request of DSS. Changes approved by DSS on June 14, 2016.
Updated	April 2017	Update to Procedure section. Added language clarifying the information needed to review requests for orthopedic

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		and diabetic shoes. Changes approved at the May 10, 2017 Medical Policy Review Committee meeting. Changes approved at the June 20, 2017 Clinical Quality Subcommittee meeting. Changes approved by DSS on July 14, 2017.
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