TO: ALL OFFICES

SUBJECT: MANUAL MATERIAL

OAC 317:30-3-61; 30-5-137 through 30-5-139; 30-5-210.1 through 30-5-210.2; 30-5-211.1; 30-5-211.8; 30-5-211.13 through 30-5-211.14; 30-5-211.18; 30-5-212; and 30-5-216.

EXPLANATION: Policy revisions were approved by the Board and the Governor as required by the Administrative Procedures Act.

Rules are revised to include an agency model for administration and operation of a program for self-direction. All programs implementing the self-direction option must adhere to the requirements of this policy. Self-direction is a method of service delivery that allows members, supports and services they need to live successfully in a home and community based setting.

Durable medical equipment (DME) rules are written to establish a policy of ownership for all purchased durable medical equipment, prosthetics, orthotics, and supplies. This rule allows all durable medical equipment purchased by SoonerCare to remain the property of OHCA to be used for the benefit of the requesting member is the first rule in complying with Oklahoma state law (56 O.S. 1011.11) mandating OHCA to promulgate rules and establish procedures necessary to implement a durable medical equipment retrieval program.

Durable medical equipment (DME) rules are revised to provide further clarification in regards to the services available to adults and the additional services available to children. These revisions will further align policy with reimbursement practices and help alleviate confusion to the provider community. Revisions include specifying general coverage for adults, providing definition and clarification in regards to adult coverage of prosthetic and orthotic devices, specifying general coverage for children, and general policy cleanup as it relates to these sections.

Bariatric surgery rules are revised to re-order the prior authorization process in policy and provide further clarification of the prior authorization process. This revision effectively re-orders policy to
present member candidacy guidelines prior to presenting coverage guidelines. This will facilitate the current prior authorization process and encourage providers to request a member candidacy prior authorization before requesting the prior authorization for the surgery. These revisions are not changing the prior authorization process, only reinforcing the current process.
INSTRUCTIONS FOR FILING MANUAL MATERIAL

OAC is the acronym for Oklahoma Administrative Code. If OAC appears before a number on an Appendix or before a Section in text, it means the Appendix or text contains rules or administrative law. Lengthy internal policies and procedures have the same Chapter number as the OAC Chapter to which they pertain following an "OKDHS" number, such as personnel policy at OKDHS:2-1 and personnel rules at OAC 340:2-1. The "340" is the Title number that designates OKDHS as the rulemaking agency; the "2" specifies the Chapter number; and the "1" specifies the Subchapter number.

The chronological order for filing manual material is: (1) OAC 340 by designated Chapter and Subchapter number; (2) if applicable, OKDHS numbered text for the designated Chapter and Subchapter; and (3) all OAC Appendices with the designated Chapter number. For example, the order for filing personnel policy is OAC 340:2-1, OKDHS:2-1, and OAC 340:2 Appendices behind all Chapter 2 manual material. Any questions or assistance with filing manual material will be addressed by contacting Policy Management Unit staff at 405-521-4326.

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317:30-3-61. Self-Directed Services

(a) Agency Model. The OHCA Self-Direction Model is an overarching set of guidelines to standardize policy for all self-directed service programs operated through the SoonerCare program. The following rules set forth minimum requirements to which all self-directed service programs must adhere. As the infrastructure for new or renewing self-direction programs is developed, the following elements will serve as a template for the programs to follow.

(b) Definitions.

1. "Financial Management Service" (FMS) is defined as a fiscal intermediary that provides at a minimum, accounting, billing and payroll services on behalf of the member, for reimbursement through the OHCA.
2. "Program" is defined as a set of benefits offered to a specific population of SoonerCare members (the program can be operated by the OHCA or another agency partner).
3. "Rendering provider" is defined as the actual deliverer of allowable goods or services.
4. "Self-Direction" is defined as a method of service delivery that allows members to determine what supports and services they need to live successfully in a home and community based setting.

(c) Member processes. The program will establish, at a minimum, the following processes for members who choose to self direct:

1. The program will establish requirements for member eligibility including a process for evaluating member needs. These requirements will also include a process for denial of eligibility.
2. The program will determine detailed benefit packages and will specify allowable goods and services available to members.
3. The program will define the member's options for self-direction. These will vary according to the approved benefit package. At a minimum, the options for self-direction will include:
   (A) training for members that is appropriate to the care provided;
   (B) utilization of a Financial Management Service (FMS) for purposes of payroll and payment to vendors. The FMS may also provide other services as determined by the individual program;
   (C) detailed description demonstrating that members have freedom of choice under all levels of self-direction options offered;
   (D) for security and auditing purposes, the program will design and implement a system for verification of services in accordance with CMS standards; and
(E) designate methods of outreach to inform members and potential members of available services, emergency procedures, concerns and general information.

(d) Provider processes. The program will establish minimum criteria for providers. These criteria will be specific to provider type and at a minimum include:

(1) training appropriate to each level of service to be provided;
(2) credentialing or licensure by a recognized state agency, if applicable to the provider type and duties;
(3) establish and specify an appropriate provider type and specialty code to apply to approved providers for the program. This provider type and specialty code must meet requirements for data integrity and auditing purposes.
(4) specify the minimum and maximum allowed rates for providers by provider type. Rates will be governed by guidelines determined by the program within approved limits and budget allowances. The program will also establish an appropriate methodology for fees paid to the FMS for administration of payroll, accounting and any other contracted duties;
(5) provider contracts with the OHCA or with a contracted agency operating as an Organized Health Care Delivery System (OHCDS);
(6) establish a provider enrollment process. At a minimum, the process shall include the following:
   (A) all rendering providers will be entered into the OHCA provider tracking system and given a unique rendering provider ID number. In instances of an Organized Health Care Delivery System, the OHCDS will be considered the rendering provider for purposes of enrollment.
   (B) the FMS will be entered into the OHCA provider tracking system and given a unique provider ID number as the billing or group provider;
   (C) all rendering providers must pass a background investigation prior to employment.

(e) Provider selection & outreach.

(1) The program will identify methods for assisting members in provider selection.
(2) The program will determine processes for informing and recruiting providers.
(3) The program will develop processes for provider communication to inform providers of procedures, concerns and general information.

(f) Claims filing process.

(1) The program will ensure claims are billed to the OHCA from the FMS and processed through the OHCA claims tracking system.
(2) The program will have appropriate procedure codes with necessary modifiers for each benefit in the program.

(3) Procedure codes must provide sufficient detail to allow for claims identification in the OHCA claims tracking system (all claims must have at least a billing, rendering and pay to).

(g) **Claims payment processes for providers, agents and agencies.**

Payments for rendering providers must be paid through an FMS. The program will establish the payment options for the FMS to utilize for paying the rendering providers.

(h) **Payment processes for alternative goods & services.** Some programs may allow for non-traditional services and alternative sources for goods with approval. The program shall determine the process for the payment of these alternative benefits with the following restrictions:

1. Identify appropriate procedure codes with necessary modifiers to allow claims to be processed and identified in the OHCA claims tracking system;
2. Prior authorization for alternative goods and services and payment made directly to the vendor. No payment for goods or services will be made to the member.
MEDICAL PROVIDERS-FEE FOR SERVICE  OAC 317:30-5-137

317:30-5-137. Eligible providers to perform bariatric surgery

The Oklahoma Health Care Authority (OHCA) covers bariatric surgery under certain conditions as defined in this section. Bariatric surgery is not covered for the treatment of obesity alone. To be eligible for reimbursement, bariatric surgery providers must be certified by the American College of Surgeons (ACS) as a Level I Bariatric Surgery Center or certified by the American Society for Bariatric Surgery as a Bariatric Surgery Center of Excellence (BSCOE) or the surgeon and facility are currently participating in a bariatric surgery quality assurance program and a clinical outcomes assessment review. All qualifications must be met and approved by the OHCA. Bariatric surgery facilities and their providers must be contracted with OHCA.
317:30-5-137.1. Member candidacy

Documentation must be submitted to the OHCA prior authorization unit prior to beginning any treatment program to ensure all requirements are met and the member is an appropriate candidate for bariatric surgery. This is the first of two prior authorizations required to approve a member for bariatric surgery. To be considered, members must meet the following candidacy criteria:

1. be between 18 and 65 years of age;
2. have body mass index (BMI) of 35 or greater;
3. be diagnosed with one of the following:
   (A) diabetes mellitus;
   (B) degenerative joint disease of a major weight bearing joint(s). The member must be a candidate for joint replacement surgery when optimal weight loss is achieved; or
   (C) a rare co-morbid condition in which there is medical evidence that bariatric surgery is medically necessary to treat such a condition and that the benefits of bariatric surgery outweigh the risk of surgical mortality.
4. have presence of obesity that has persisted for at least 5 years;
5. have attempted weight loss in the past without successful long term weight reduction, which must be documented by a physician;
6. have absence of other medical conditions that would increase the member's risk of surgical mortality or morbidity; and
7. the member is not pregnant or planning to become pregnant in the next two years.
317:30-5-137.2. General coverage

(a) After receiving member candidacy prior authorization from OHCA and the determination that member candidacy requirements are met (see OAC 317:30-5-137.1), the primary care provider coordinates a pre-operative assessment and weight loss process to include:

1. a comprehensive psychosocial evaluation including:
   (A) evaluation for substance abuse;
   (B) evaluation for psychiatric illness which would preclude the member from participating in pre-surgical weight loss and evaluation program or successfully adjusting to the post surgical lifestyle changes;
   (C) if applicable, documentation that the member has been successfully treated for a psychiatric illness and has been stabilized for at least six months; and
   (D) if applicable, documentation that the member has been rehabilitated and is free from drug and/or alcohol for a period of at least one year.

2. an independent medical evaluation performed by an internist experienced in bariatric medicine who is contracted with the OHCA to assess the member=s operative morbidity and mortality risks.

3. a surgical evaluation by an OHCA contracted surgeon who has credentials to perform bariatric surgery.

4. participation in a six month weight loss program prior to surgery, under the supervision of an OHCA contracted medical provider. The member must, within 180 days from the initial or member candidacy prior authorization approval, lose at least five percent of member=s initial body weight.

(b) When all requirements have been met, a prior authorization for surgery must be obtained from OHCA. This authorization can not be requested before the initial 180 day weight loss program has been completed.

1. If the member does not meet the weight loss requirement in the allotted time the member will not be approved for bariatric surgery.

2. The member=s provider must restart the prior authorization process if this requirement is not met.

(c) The bariatric surgery facility or surgeon must, on an annual basis, provide to the OHCA the members statistical data which includes but is not limited to, mortality, hospital readmissions, re-operation, morbidity and average weight loss data.

(d) OHCA considers surgery to correct complications from bariatric surgery, such as obstruction or stricture, medically necessary.

(e) OHCA considers repeat bariatric surgery medically necessary for a member whose initial bariatric surgery was medically necessary.
and member meets either of the following criteria:
   (1) has not lost more than fifty percent of excess body weight two years following the primary bariatric surgery procedure and is in compliance with prescribed nutrition and exercise programs following the procedure; or
   (2) failure due to dilation of the gastric pouch if the initial procedure was successful in inducing weight loss prior to the pouch dilation and the member is in compliance with prescribed nutrition and exercise programs following the initial procedure.
(f) OHCA may withdraw authorization of payment for the bariatric surgery at any time if the OHCA determines that the member or provider is not in compliance with any of the requirements.
317:30-5-210.1. Coverage for adults

Coverage of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) for adults is specified in OAC 317:30-5-211.1 through OAC 317:30-5-211.18.
317:30-5-210.2. Coverage for children

(a) Coverage. Coverage of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) for children includes the specified coverage for adults found in OAC 317:30-5-211.1 through OAC 317:30-5-211.18. In addition the following are covered items for children only:

(1) Orthotics and prosthetics.
(2) Enteral nutrition is considered medically necessary for certain conditions in which, without the products, the member's condition would deteriorate to the point of severe malnutrition.

(A) Enteral nutrition must be prior authorized. PA requests must include:

(i) the member's diagnosis;
(ii) the impairment that prevents adequate nutrition by conventional means;
(iii) the member's weight history before initiating enteral nutrition that demonstrates oral intake without enteral nutrition is inadequate;
(iv) the percentage of the member's average daily nutrition taken by mouth and by tube; and
(v) prescribed daily caloric intake.

(B) Enteral nutrition products that are administered orally and related supplies are not covered.

(b) EPSDT. Services deemed medically necessary and allowable under federal regulations may be covered by the EPSDT Child Health program even though those services may not be part of the SoonerCare program. These services must be prior authorized.

(c) Medical necessity. Federal regulations require OHCA to make the determination as to whether the service is medically necessary and do not require the provision of any items or services that the State determines are not safe and effective or that are considered experimental.
317:30-5-211.1. Definitions

The following words and terms, when used in this Part, have the following meaning, unless the context clearly indicates otherwise.

"Adaptive equipment" means devices, aids, controls, appliances or supplies of either a communication or adaptive type, determined necessary to enable the person to increase his or her ability to function in a home and community based setting or private Intermediate Care Facilities for the Mentally Retarded (ICF/MR) with independence and safety.

"Capped rental" means monthly payments for the use of the Durable Medical Equipment (DME) for a limited period of time not to exceed 13 months. Items are considered purchased after 13 months of continuous rental.

"Certificate of medical necessity (CMN)" means a certificate required to help document the medical necessity and other coverage criteria for selected items, those items are defined in this Chapter. The physician's certification must include the member's diagnosis, the reason the equipment is required, and the physician's estimate, in months, of the duration of its need.

"Customized DME" means items of DME which have been uniquely constructed or substantially modified for a specific member according to the description and orders of the member's treating physician. For instance, a wheelchair would be considered "customized" if it has been:

(A) measured, fitted or adapted in consideration of the member's body size, disability, period of need, or intended use;

(B) assembled by a supplier or ordered from a manufacturer who makes available customized features, modifications, or components for wheelchairs; and

(C) intended for an individual member's use in accordance with instructions from the member's physician.

"Durable medical equipment (DME)" means equipment that can withstand repeated use, i.e.; the type of item that could normally be rented is used to serve a medical purpose, is not useful to a person in the absence of an illness or injury, and is used in the most appropriate setting including the home or workplace.

"Invoice" means a document that provides the following information when applicable; description of product, quantity, quantity in box, purchase price (less any discounts, rebates or commissions received), NDC, strength, dosage, provider, seller's name and address, purchaser's name and address and date of purchase. At times, visit notes will be required to determine how much of the supply was expended. When possible, the provider
should identify the SoonerCare member receiving the equipment or supply on the invoice.

"Medical supplies" means an article used in the cure, mitigation, treatment, prevention, or diagnosis of illnesses. Disposable medical supplies are medical supplies consumed in a single usage and do not include skin care creams or cleansers. Medical supplies do not include surgical supplies or medical or surgical equipment.

"OHCA CMN" means a certificate required to help document the medical necessity and other coverage criteria for selected items. Those items are defined in this chapter. The physician's certification must include the member's diagnosis, the reason equipment is required, and the physician's estimate, in months, of the duration of its need. This certificate is used when the OHCA requires a CMN and one has not been established by CMS.

"Orthotics" means an item used for the correction or prevention of skeletal deformities.

"Prosthetic devices" means a replacement, corrective, or supportive device (including repair and replacement parts for same) worn on or in the body, to artificially replace a missing portion of the body, prevent or correct physical deformity or malfunction, or support a weak or deformed portion of the body.
317:30-5-211.13. **Prosthetics and orthotics**

Coverage of prosthetics for adults is limited to (1) home dialysis equipment and supplies, (2) nerve stimulators, (3) external breast prosthesis and support accessories, and (4) implantable devices inserted during the course of a surgical procedure. Prosthetics prescribed by an appropriate medical provider and as specified in this section are covered items for adults. There is no coverage of orthotics for adults.

1. **Home dialysis.** Equipment and supplies are covered items for members receiving home dialysis treatments only.

2. **Nerve stimulators.** Payment is made for transcutaneous nerve stimulators, implanted peripheral nerve stimulators, and neuromuscular stimulators.

3. **Breast prosthesis, bras, and prosthetic garments.**
   
   (A) Payment is limited to:
   
   (i) one prosthetic garment with mastectomy form every 12 months for use in the postoperative period prior to a permanent breast prosthesis or as an alternative to a mastectomy bra and breast prosthesis;
   
   (ii) two mastectomy bras per year; and
   
   (iii) one silicone or equal breast prosthetic per side every 24 months; or
   
   (iv) one foam prosthetic per side every six months.
   
   (B) Payment will not be made for both a silicone and a foam prosthetic in the same 12 month period.
   
   (C) Breast prostheses, bras, and prosthetic garments must be purchased from a Board Certified Mastectomy Fitter.
   
   (D) A breast prosthesis can be replaced if:
   
   (i) lost;
   
   (ii) irreparably damaged (other than ordinary wear and tear); or
   
   (iii) the member's medical condition necessitates a different type of item and the physician provides a new prescription explaining the need for a different type of prosthesis.

   (E) External breast prostheses are not covered after breast reconstruction is performed except in instances where a woman with breast cancer receives reconstructive surgery following a mastectomy, but the breast implant fails or ruptures and circumstances are such that an implant replacement is not recommended by the surgeon and/or desired by the member.

4. **Prosthetic devices inserted during surgery.** Separate payment is made for prosthetic devices inserted during the course of surgery when the prosthetic devices are not integral to the procedure and are not included in the reimbursement for the procedure itself.
317:30-5-211.14. Nutritional support

(a) Parenteral nutrition. The member must require intravenous feedings to maintain weight and strength commensurate with the member's overall health status. Adequate nutrition must not be possible by dietary adjustment and/or oral supplements.

   (1) The member must have a permanent impairment. Permanence does not require a determination that there is no possibility that the member's condition may improve sometime in the future. If the judgment of the attending physician, substantiated in the medical record, is that the condition is of long and indefinite duration (ordinarily at least three months), the test of permanence is met. Parenteral nutrition will be denied as a non-covered service in situations involving temporary impairments.

   (2) The member must have a condition involving the small intestine, exocrine glands, or other conditions that significantly impair the absorption of nutrients. Coverage is also provided for a disease of the stomach and/or intestine that is a motility disorder and impairs the ability of nutrients to be transported through the GI system, and other conditions as deemed medically necessary. There must be objective medical evidence supporting the clinical diagnosis.

   (3) Re-certification of parenteral nutrition will be required as medically necessary and determined by the OHCA medical staff.

(b) Prior authorization. A written signed and dated order must be received by the supplier before a claim is submitted to the OHCA. If the supplier bills an item addressed in this policy without first receiving the completed order, the item will be denied as not medically necessary. The ordering physician is expected to see the member within 30 days prior to the initial certification or required re-certification. If the physician does not see the member within this time frame, the physician must document the reason why and describe what other monitoring methods were used to evaluate the member's parenteral nutrition needs.

(c) Enteral formulas. Enteral formulas are covered for children only. See OAC 317:30-5-210.2.
317:30-5-211.18. Ownership of durable medical equipment

Durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) purchased by SoonerCare are the property of the Oklahoma Health Care Authority (OHCA) to be used for the benefit of the requesting member until it is no longer medically necessary. At such time as the item is no longer medically necessary, OHCA or an OHCA contractor may retrieve the DMEPOS product if it is determined to be administratively and fiscally prudent.
317:30-5-216. Prior authorization requests

(a) Prior authorization requirements. Requirements vary for different types of services. Providers should refer to the service-specific sections of policy or the OHCA website for services requiring PA.

(1) Required forms. Form HCA-12A may be obtained at local county OKDHS offices and is available on the OHCA web site at www.okhca.org.

(2) Certificate of medical necessity. The prescribing provider must complete the medical necessity section of the CMN. This section cannot be completed by the supplier. The medical necessity section can be completed by any health care clinician; however, only the member's treating provider may sign the CMN. By signing the CMN, the physician is validating the completeness and accuracy of the medical necessity section. The member's medical records must contain documentation substantiating that the member's condition meets the coverage criteria and the answers given in the medical necessity section of the CMN. These records may be requested by OHCA or its representatives to confirm concurrence between the medical records and the information submitted with the prior authorization request.

(b) Submitting prior authorization requests. Contact information for submitting prior authorization requests may be found in the OHCA Provider Billing and Procedures Manual. An electronic version of this manual is located on the OHCA web site.

(c) Prior authorization review. Upon verifying the completeness and accuracy of clerical items, the PA request is reviewed by OHCA staff to evaluate whether or not each service being requested meets SoonerCare's definition of "medical necessity" [see OAC 317:30-3-1 (f)] as well as other criteria.

(d) Prior authorization decisions. After the HCA-12A is processed, a notice will be issued advising whether or not the item is authorized. If authorization is issued, the notice will include an authorization number, the time period for which the device is being authorized and the appropriate procedure code.

(e) Prior authorization does not guarantee reimbursement. Provider status, member eligibility, and medical status on the date of service, as well as all other SoonerCare requirements, must be met before the claim is reimbursed.

(f) Prior authorization of manually-priced items. Manually-priced items must include documentation showing the supplier's Manufacturer's Suggested Retail Price (MSRP) of the item with the request for prior authorization. The MSRP must be listed for each item in the "billed charges" box on the HCA-12A. If an item does not have an MSRP, the provider must include a copy of the current
invoice indicating the cost to the provider and a statement from the manufacturer that there is no MSRP available. Reimbursement will be determined as per OAC 317:30-5-218.