Oklahoma Health Care Authority

It is very important that you provide your comments regarding the proposed rule change by the comment due date. Comments are directed to Oklahoma Health Care Authority (OHCA) Health Policy Unit http://www.okhca.org/proposed-rule-changes.aspx

OHCA COMMENT DUE DATE: February 16, 2015.

The proposed policy is a Permanent Rule. This proposal is scheduled to be presented to the Medical Advisory Committee (MAC) on March 12, 2015 and the (OHCA) Board of Directors on March 26, 2015.

Reference: APA WF 14-28

SUMMARY:
Allergy Testing Rules-Rules are added to regulate allergy testing and immunotherapy services. Current policy does not specify controls on these services other than general medical necessity.

LEGAL AUTHORITY:
The Oklahoma Health Care Authority Board; The Oklahoma Health Care Authority Act, Section 5003 through 5016 of Title 63 of Oklahoma Statutes; 42 CFR 440.50.

RULE IMPACT STATEMENT:

TO: Tywanda Cox
Health Policy

FROM: Likita Gunn
Health Policy

SUBJECT: Rule Impact Statement
APA WF 14-28

A. Brief description of the purpose of the rule:

The Agency's rules are revised to establish policy for the appropriate administration of allergy testing and immunotherapy services. Criteria include: definition of allergy testing and immunotherapy, coverage requirements, non-covered services, reimbursement conditions, appropriate delivery sites, provider qualifications, and documentation requirements for home administration of immunotherapy.

Additionally, revisions include clean-up to remove allergy reimbursement language from injection policy as it is referenced in the new section.

B. A description of the classes of persons who most likely will be affected by the proposed rule, including classes that will bear the cost of the proposed rule, and any information on cost impacts received by the agency from any private or public entities:

SoonerCare providers administering allergy testing without documented training and/or certification in the diagnosis and treatment of allergy and immunotherapy services, will be impacted by the proposed rule.

C. A description of the classes of persons who will benefit from the proposed rule:

No classes of persons will benefit from the proposed rule.

D. A description of the probable economic impact of the proposed rule upon the affected classes of persons or political subdivisions, including a listing of all fee changes and, whenever possible, a separate justification for each fee change:

There is no probable economic impact of the proposed rule upon any classes of persons or political subdivisions. There are no fee changes associated with the proposed rule revisions.

E. The probable costs and benefits to the agency and to any other agency of the implementation and enforcement of the proposed rule, the source of revenue to be used for implementation and enforcement of the proposed rule, and any anticipated affect on state revenues, including a projected net loss or gain in such revenues if it can be projected by the agency:

The Agency has determined that there are no probable net costs to OHCA or other agencies expected as a result of the proposed rules nor is there an anticipated effect on State revenues.

F. A determination of whether implementation of the proposed rule will have an economic impact on any political

subdivisions or require their cooperation in implementing or enforcing the rule:

There is no economic impact on political subdivisions.

G. A determination of whether implementation of the proposed rule will have an adverse effect on small business as provided by the Oklahoma Small Business Regulatory Flexibility Act:

The proposed rule will not have an adverse effect on small businesses as provided by the Oklahoma Small Business Regulatory Flexibility Act.

H. An explanation of the measures the agency has taken to minimize compliance costs and a determination of whether there are less costly or non-regulatory methods or less intrusive methods for achieving the purpose of the proposed rule:

The agency has taken measures to determine that there is no less costly or non-regulatory method or less intrusive method for achieving the purpose of the proposed rule.

I. A determination of the effect of the proposed rule on the public health, safety and environment and, if the proposed rule is designed to reduce significant risks to the public health, safety and environment, an explanation of the nature of the risk and to what extent the proposed rule will reduce the risk:

The proposed rule should have no adverse effect on the public health, safety, and environment.

J. A determination of any detrimental effect on the public health, safety and environment if the proposed rule is not implemented:

The Agency does not anticipate any detrimental effects on the public health, safety, or environment if the proposed rule is not implemented.

K. The date the rule impact statement was prepared and if modified, the date modified:

The rule impact statement was prepared December 12, 2014.

RULE TEXT:

TITLE 317. OKLAHOMA HEALTH CARE AUTHORITY
CHAPTER 30. MEDICAL PROVIDERS-FEE FOR SERVICE
SUBCHAPTER 5. INDIVIDUAL PROVIDERS AND SPECIALTIES
PART 1. PHYSICIANS

317:30-5-14. Injections

(a) Coverage for injections is limited to those categories of drugs included in the vendor drug program for SoonerCare. SoonerCare payment is not available for injectable drugs whose manufacturers have not entered into a drug rebate agreement with the Centers for Medicare and Medicaid Services (CMS). OHCA administers and maintains an open formulary subject to the provisions of Title 42, United States Code (U.S.C.), Section 1396r-8. The OHCA covers a drug that has been approved by the Food and Drug Administration (FDA) subject to the exclusions and limitations provided in OAC 317:30-5-72.1.

(1) **Immunizations for children.** An administration fee will be paid for vaccines administered by providers participating in the Vaccines for Children Program. For vaccines administered as part of the Vaccines for Children Program, only one administration fee is permitted per vaccine, regardless of the number of vaccine/toxoid components in the vaccine. Payment will not be made for vaccines covered by the Vaccines for Children Program. When the vaccine is not included in the program, the administration fee is separately payable.

(2) **Immunizations for adults.** Coverage for adults is provided as per the Advisory Committee on Immunization Practices (ACIP) guidelines. A separate payment will be made for the administration of a vaccine. Only one administration fee per vaccine is permitted, regardless of the number of vaccine/toxoid components in the vaccine.

(b) Providers must use the appropriate HCPCS code and National Drug Code (NDC). In addition to the NDC and HCPCS code, claims must contain the drug name, strength, and dosage amount.

~~(c) Payment is made for allergy injections for adults and children. When the contracted provider actually administers or supervises the administration of the injection, the administration fee is compensable. No payment is made for administration when the allergy antigen is self-administered by the member. When the allergy antigen is purchased by the physician, payment is made by invoice attached to the claim.~~

~~(d)~~(c) Rabies vaccine, Imovax, Human Diploid and Hyperab, Rabies Immune Globulin are covered under the vendor drug program and may be covered as one of the covered prescriptions per month. Payment can be made separately to the physician for administration. If the vaccine is purchased by the physician, payment is made by invoice attached to the claim.

~~(e)~~(d) Human Papillomavirus (HPV) vaccine is approved and covered under guidelines established by the ACIP for children and adults. Payment can be made separately to the physician for administration and the vaccine product.
~~(f)~~(e)Trigger point injections (TPI's) are covered using appropriate CPT codes. Modifiers are not allowed for this code. Payment is made for up to three injections (3 units) per day at the full allowable. Payment is limited to 12 units per month. The medical records must clearly state the reasons why any TPI services were medically necessary. All trigger point records must contain proper documents and be available for review. Any services beyond 12 units per month or 36 units per 12 months will require mandatory review for medical necessity. Medical records must be automatically submitted with any claims for services beyond 36 units.
~~(g)~~(f)If a physician bills separately for surgical injections and identifies the drugs used in a joint injection, payment will be made for the cost of the drug in addition to the surgical injection. The same guidelines apply to aspirations.
~~(h)~~(g) When IV administration in a Nursing Facility is filed by a physician, payment may be made for medication. Administration should be done by nursing home personnel.
~~(i)~~(h) Intravenous fluids used in the administration of IV drugs are covered. Payment for the set is included in the office visit reimbursement.
~~(j)~~(i) In the event a pandemic virus is declared by the Centers for Disease Control (CDC) and/or the Department of Health & Human Services, an administration fee will be paid to providers for administering the pandemic virus vaccine to adults and children as authorized by the Centers for Medicare and Medicaid Services (CMS).

317:30-5-14.1 Allergy Services

(a) **Allergy testing.** Allergy testing is the process of identifying allergen(s) that may cause an allergic or anaphylactic reaction and the degree of the reaction. By identifying the allergen(s), the member can avoid exposures and the allergic reaction can be managed appropriately. Treatment options for allergies are avoidance of the allergen(s), pharmacological therapy, and/or immunotherapy. OHCA may consider allergy testing medically necessary when a complete medical, immunological history, and physical examination is performed and indicates symptoms are suggestive of a chronic allergy. Allergy testing may also be determined medically necessary if diagnosis indicates an allergy and simple medical treatment and avoidance of the allergen(s) were tried and showed inadequate response.

(1) **Coverage**. OHCA will provide reimbursement for allergy testing when the following conditions are met:

(A) Testing is done in a hospital or providers office under direct supervision of an eligible provider;

(B) The diagnostic testing is based on the member's immunologic history and physical examination, which document that the antigen(s) being used for testing have a reasonable probability of exposure in the members environment;

(C) The member has significant life-threatening symptomatology or a chronic allergic state (e.g., asthma) which has not responded to conservative measures;

(D) The member's records document the need for allergy testing and the justification for the number of tests performed;

(E) The complete report of the test results, as well as controls, will be kept as part of the medical record; and

(F) The member is observed for a minimum of 20 minutes following allergy testing to monitor for signs of allergic or anaphylactic reactions.

(2) **Provider requirements**. Only contracted providers (a physician (MD or DO), physician's assistant, or advanced practice nurse) who have documented training and/or certification in the diagnosis and treatment of allergy and immunotherapy are reimbursed for performing allergy testing and antigen(s) preparation.

(A) Follow-up administration of medically indicated allergy immunotherapy can be done by a practitioner other than an allergist.

(B) Allergy testing and/or immunotherapy for SoonerCare members younger than five years of age preferably should be performed by an allergy specialist.

(3) **Description of services**. There are a variety of tests to identify the allergen(s) that may be responsible for the member's allergic response. OHCA covers the following allergy test(s) for SoonerCare members:

(A) Direct skin tests:

(i) Percutaneous (i.e., scratch, prick, or puncture) tests are performed for inhalant allergies, suspected food allergies, hymenoptera allergies, or specific drug allergies.

(ii) Intra-cutaneous (i.e., intradermal) tests are performed commonly when a significant allergic history is obtained and results of the percutaneous test are negative or equivocal.

(B) Patch or application tests;

(C) Photo or photo patch skin tests;

(D) Inhalant bronchial challenge testing (not including necessary pulmonary function tests);
(E) Ingestion challenge tests (this test is used to confirm an allergy to a food or food additives); and
(F) Double-blind food challenge testing.
(G) Ophthalmic mucous membrane or direct nasal membrane tests, serum allergy tests, serial dilution endpoint tests, or any unlisted allergy procedure not stated above will require prior authorization.

(4) **Reimbursement.** Reimbursement for allergy testing is limited to a total of 60 tests every three years. Repeat allergy testing for the same allergen(s) within three years will require prior authorization. Any service related to allergy testing beyond predetermined limits must be submitted with the appropriate documentation to OHCA for prior authorization consideration.

(5) **Non-covered services.** OHCA does not cover allergy testing determined to be investigational or experimental in nature.

(b) **Allergy immunotherapy.** Allergy immunotherapy involves administration of allergenic extracts at periodic intervals, with the goal of reducing symptoms, including titrating to a dosage that is maintained as maintenance therapy. Allergy immunotherapy is initiated once the offending allergen(s) has been identified through exposure and/or allergy testing. The documented allergy should correspond to the allergen planned for immunotherapy. OHCA may consider allergy immunotherapy medically necessary for members who have significant life-threatening symptomology or a chronic allergic state that cannot be managed by medication, avoidance, or environmental control measures. Before beginning allergy immunotherapy, consideration must be given to other common medical conditions that could make allergy immunotherapy more risky.

(1) **Coverage requirements.** Allergy immunotherapy is covered when the following criteria are met and documented in the medical record:
(A) The member has allergic asthma, or
(B) Allergic rhinitis and/or conjunctivitis, or
(C) Life-threatening allergy to hymenoptera (stinging insect allergy), or
(D) There is clinical evidence of an inhalant allergen(s) sensitivity; and
(E) Documentation supports that the member's symptoms are not controlled with medications and avoidance of the allergen(s) are impractical.

(2) **Provider qualifications.** See OAC 317:30-5-14.1(A)(2) for provider qualifications.

(3) **Administering sites.** Allergy immunotherapy should be administered in a medical facility with trained staff and proper medical equipment available in the case of significant reaction. Should home administration be necessary, the following requirements must be met:

(A) Adequate documentation must be present in the member's record indicating why home administration is medically necessary;

(B) Documentation must indicate the member and/or family member have been properly trained in recognizing and treating anaphylactic and/or allergic reactions to allergy immunotherapy administration;

(C) Epinephrine kits must be available to the member and the family and the member and/or family have been instructed in its use;

(D) Documentation of member and/or family member having been properly trained in antigen(s) dosing plan, withdrawing of correct amount of antigen(s) from the vial and administration of allergy immunotherapy;

(E) The signed consent by the member or family member to administer allergy immunotherapy at home;

(F) The provider initiated allergy immunotherapy in their office and is planning to continue therapy at the member's home; and

(G) Signed acknowledgement by the member or family member of receiving antigen vial(s) as per treatment protocol.

(4) **Treatment period.** A "treatment period" is generally 90 days, and adequate documentation must be available for continuation of therapy after each treatment period. The length of allergy immunotherapy treatment depends on the demonstrated clinical efficacy of the treatment.

(5) **Reimbursement**. Payment is made for the administration of allergy injections as well as supervision and provision of antigen(s) for adults and children, with the following considerations:

(A) When a contracted provider actually administers or supervises administration of the allergy injections, the administration fee is compensable;

(B) Reimbursement for the administration only codes is limited to one per member, per day;

(C) No reimbursement is made for administration of allergy injections when the allergy injection is self-administered by the member; and

(D) For antigens purchased by the provider for supervision, preparation and provision for allergy immunotherapy, an invoice reflecting the purchase should be made available upon request for post-payment review.

(6) **Limitations.** The following limitations and restrictions apply to immunotherapy:

(A) A presumption of failure can be assumed if, after 12 months of allergy immunotherapy, the member does not experience any signs of improvement, and all other reasonable factors have been ruled out.

(B) Documented success of allergy immunotherapy treatment is evidenced by:

(i) A noticeable decrease of hypersensitivity symptoms, or

(ii) An increase in tolerance to the offending allergen(s), or

(iii) A reduction in medication usage.

(C) Very low dose immunotherapy or continued submaximal dose has not been shown to be effective and will be denied as not medically necessary.

(D) Liquid antigen(s) prepared for sublingual administration are not covered as they have not been proven to be safe and effective.

(E) Food and Drug Administration (FDA) approved oral desensitization therapies may be covered as part of the member's pharmacy benefits and requires prior authorization.

(F) If a provider is preparing single dose vials of antigens to be administered by a different provider, member or family member, only 30 units per treatment period of 90 days with a limit of 120 units per year is allowed. Additional units above the stated limits will require prior authorization.

(G) If using multi-dose vials, there is a limitation of 10 units per vial, with a maximum of 20 units allowed per 90 day treatment period. There is a limit of 80 units allowed per year. Additional units above the stated limits will require prior authorization.

(7) **Non-covered services.** Allergy immunotherapy determined by OHCA to be investigational or experimental will not be covered.