5160-4-12 **Immunizations, injections and infusions (including trigger-point injections), skin substitutes, and provider-administered pharmaceuticals.**

(A) General provisions.

(1) "Current procedural terminology (CPT)" is a comprehensive listing of medical terms and codes published by the American medical association, www.ama-assn.org, for the uniform designation of diagnostic and therapeutic procedures in surgery, medicine, and the medical specialties. "Healthcare common procedure coding system (HCPCS)" is a numeric and alphanumeric code set maintained and distributed by the centers for medicare and medicaid services (CMS), http://www.cms.gov, for the uniform designation of certain medical procedures and services.

(2) A "not otherwise specified," "unlisted," or "miscellaneous" procedure code should be reported on a claim only if no procedure code is available that identifies the particular service or item provided.

(3) No separate payment is made for an immunization, injection, infusion, vaccine, toxoid, or provider-administered pharmaceutical as a medical service if it is provided in a hospital setting (inpatient hospital, outpatient hospital, or hospital emergency department).

(4) A provider-administered pharmaceutical reported on a claim submitted in accordance with Chapter 5160-9 of the Administrative Code is regarded as a pharmacy service rather than a physician service, and payment of the claim is governed by the provisions of that chapter. For example, a vaccine, toxoid, or other provider-administered pharmaceutical prescribed for a resident of a long-term care facility (LTCF) and subsequently administered by a LTCF staff member is a pharmacy service.

(5) Payment for an immunization, injection, or infusion includes payment for related supplies (e.g., alcohol wipes, needles, syringes, and tubing).

(B) Coverage of immunizations. An immunization has two components: the administration of the vaccine or toxoid and the vaccine or toxoid itself.

(1) Payment for administration may take one of two forms:

(a) Payment for the most appropriate administration procedure; or

(b) Payment for the least complex evaluation and management service

rendered to an established patient.

(2) Separate payment may be made for the vaccine or toxoid. No payment, however, will be made for vaccines that can be obtained at no cost through the federal vaccines for children (VFC) program, which is administered by the Ohio department of health (ODH).

(3) Limitations based on age or gender apply to certain vaccines.

(a) Regardless of the formulation, payment for hepatitis B vaccine (HBV) administered to individuals younger than nineteen years of age may be made only under the VFC program. Different procedure codes must be reported on claims to distinguish HBV administered to individuals younger than nineteen from HBV administered to individuals older than eighteen.

(b) Both the quadrivalent vaccine and the nine-valent vaccine for the human papilloma virus (HPV) are covered for both males and females from nine through twenty-one years of age. ~~For both males and females who are eligible for medicaid only through the family planning services benefit, coverage extends through twenty-six years of age.~~

(c) The bivalent vaccine for HPV is covered for females from nine through twenty-one years of age. ~~For females who are eligible for medicaid only through the family planning services benefit, coverage extends through twenty-six years of age.~~ This vaccine is not covered for males.

(C) Coverage of therapeutic, prophylactic, or diagnostic injections or infusions (excluding chemotherapy and other complex procedures).

(1) An injection or infusion has two components: the administration of a fluid medium and, except in the case of hydration, the pharmaceutical itself. No separate payment is made for the administration service if an injection or infusion is given during the course of an office visit or in conjunction with another medical service that includes an evaluation and management element.

(2) Payment may be made for an injection or infusion or a provider-administered pharmaceutical only if at least one of the following criteria is met:

(a) Its use for a particular indication has been approved by the U.S. food and drug administration; or

(b) According to accepted standards of medical practice, it is a specific or effective treatment for the particular condition for which it is given.

(3) No separate payment is made for an injection or infusion or a provider-administered pharmaceutical that meets either of the following criteria:

(a) The frequency or duration of its administration exceeds accepted standards of medical practice for the particular condition; or

(b) It is provided for or in association with noncovered medicaid services, which are defined in rule 5160-4-28 of the Administrative Code.

(4) Immune globulin is covered when it is used to provide passive immunity to an individual who is immunosuppressed; has an acquired or congenital immunodeficiency; is at risk of Rho(D) isoimmunization; or is in immediate danger of contracting a communicable disease through direct contact with blood, saliva, or other body fluids through an open wound, bite, puncture, or mucous membrane.

(5) Epoetin alfa (EPO) for the treatment of anemia, either associated with or not related to chronic renal failure, is covered as a medical service when a provider incurs the cost of the drug and the service is provided in a clinic (e.g., a renal dialysis facility) or office setting.

(6) Certain procedure codes represent a specific number of dosage units. On a claim, the fewest number of procedure codes must be reported together to represent the administered dosage.

(D) Coverage of trigger-point injections.

(1) A trigger point is a hyperexcitable area of the body, where the application of a stimulus will provoke pain to a greater degree than in the surrounding area. The purpose of a trigger-point injection is to treat not only the symptom but also the cause through the injection of a single substance (e.g., a local anesthetic) or a mixture of substances (e.g., a corticosteroid with a local anesthetic) directly into the affected body part in order to alleviate inflammation and pain. Payment may be made for a trigger-point injection only if the following criteria are met:

(a) The patient must have a diagnosis for which the trigger-point injection is

an appropriate treatment; and

(b) The following information must be documented in the patient's medical record:

(i) A proper evaluation including a patient history and physical examination leading to diagnosis of the trigger point;

(ii) The reason or reasons for selecting this therapeutic option;

(iii) The affected muscle or muscles;

(iv) The muscle or muscles injected and the number of injections;

(v) The frequency of injections required;

(vi) The name of the medication used in the injection;

(vii) The results of any prior treatment; and

(viii) Corroborating evidence that the injection is medically necessary.

(2) A trigger-point injection is normally considered to be a stand-alone service. No additional payment will be made for an office visit on the same date of service unless there is an indication on the claim (e.g., in the form of a modifier appended to the evaluation and management procedure code) that a separate evaluation and management service was performed.

(3) Certain trigger-point injection procedure codes specify the number of injection sites. For these codes, the unit of service is different from the number of injections given. Payment may be made for one unit of service of the appropriate procedure code reported on a claim for service rendered to a particular patient on a particular date.

(4) Trigger-point injections should be repeated only if doing so is reasonable and medically necessary. For trigger-point injections of a local anesthetic or a steroid, payment will be made for no more than eight dates of service per calendar year per patient.

(E) Coverage of skin substitutes.

(1) Skin substitutes for wound treatment and healing are covered in an office setting in conjunction with standard wound care regimens for the treatment of burns or ulcers. Payment may be made to the practitioner when the practitioner utilizes a skin substitute product along with the performance of a valid skin application procedure. Skin substitutes are covered for the treatment of ulcers when a professional practitioner determines a skin substitute will benefit the type of ulcer. Applications and re-applications must show improvement in accordance with paragraph (E)(6) of this rule.

(2) Skin substitutes may be used on burns when skin grafting is not the appropriate option. These covered bioengineered skin substitutes are expected to function as a permanent replacement for lost or damaged skin. They may be used for temporary wound coverage or wound closure as appropriate and medically necessary.

(3) No separate payment is made to a hospital for the supply of skin substitute grafts provided in hospital settings (inpatient hospital, outpatient hospital or hospital emergency department). Payment for the products is included in the hospital's facility payment. When a practitioner applies the skin substitute grafts in a hospital setting, only the professional application procedure is reimbursable to the practitioner.

(4) No separate payment is made to a LTCF for the supply of skin substitute grafts provided by a LTCF for residents of a LTCF. Payment for these products is included in the LTCF payment. Except as provided in paragraph (E)(5) of this rule, when a practitioner applies skin substitute grafts in a LTCF setting, only the professional application procedure is reimbursable to the practitioner.

(5) The supply of skin substitute grafts may be separately reimbursable to a professional practitioner administering wound treatment in a LTCF only when the product is supplied by the practitioner in conjunction with the application of the skin substitute grafting procedure as described in the integumentary system section of the CPT. Payment may be made to the practitioner when the practitioner utilizes a skin substitute product along with the performance of a valid skin application procedure.

(6) If skin substitute applications and re-applications show no significant improvement after three separate treatments, additional re-applications are inappropriate and other treatment modalities should be considered. Skin substitute treatments should not last more than twelve weeks. A decrease of fifty per cent or greater in wound volume must be documented in the medical records for the reimbursement of additional re-applications after twelve weeks of treatment. If after twelve weeks the medical records do not support the significant improvement of the wound using the skin substitute treatments, the Ohio department of medicaid may recoup any inappropriate

reimbursement.

~~(E)~~(F) Claim payment.

(1) On the department's web site, http://medicaid.ohio.gov, is a list of vaccines, toxoids, and other provider-administered pharmaceuticals each of which is covered by medicaid either as a medical service or as a VFC-designated vaccine. Payment for a covered non-VFC vaccine, toxoid, skin substitutes, or other provider-administered pharmaceutical is the lesser of two figures:

(a) The provider's submitted charge; or

(b) The maximum allowable amount, which is the first applicable item from the following ordered list:

(i) An amount specified in or determined in accordance with the Administrative Code;

(ii) The maximum allowable cost (MAC), which is defined in Chapter 5160-9 of the Administrative Code;

(iii) The payment limit shown in the current medicare part B drug pricing file, which is available at http://www.cms.gov;

(iv) One hundred seven per cent of the wholesale acquisition cost (WAC); or

(v) Eighty-five and six-tenths per cent of the average wholesale price (AWP).

(2) The payment amount for any other covered administration service or evaluation and management service is the lesser of the provider's submitted charge or the maximum amount listed in appendix DD to rule 5160-1-60 of the Administrative Code.

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