
**INDIANA HEALTH COVERAGE PROGRAMS**

**PROVIDER REFERENCE MODULE**

# Injections, Vaccines, and Other Physician-Administered Drugs

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# Revision History

| Version | Date | Reason for Revisions | Completed By |
|---|---|---|---|
| 1.0 | Policies and procedures as of October 1, 2015<br>Published: February 25, 2016 | New document | FSSA and HPE |
| 1.1 | Policies and procedures as of April 1, 2016<br>Published: July 28, 2016 | Semiannual update:<br>• Reorganized text for better flow and made general edits throughout document<br>• Updated the *Billing Procedure Codes That Require NDCs – Professional Claim Types* section<br>• Updated note box in the *Remittance Advice and NDC-Related Edits* section<br>• Updated the *Billing and Reimbursement for Physician-Administered Drugs* section to include information about treatment room visits<br>• Updated the *Histrelin Implant (Vantas)* section with billing unit and dosage information<br>• Removed the *VFC Vaccine Storage* and *Vaccines Not Available in the United States* sections | FSSA and HPE |
| 1.1 | Policies and procedures as of April 1, 2016<br>(*Core*MMIS updates as of February 13, 2017)<br>Published: March 28, 2017 | • Added Provider Healthcare Portal instructions for billing<br>• Removed ICD-9 information<br>• Updated Customer Assistance and TPL Unit telephone numbers<br>• Updated information in the *Remittance Advice and NDC-Related Explanations of Benefits* section | FSSA and HPE |

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# Injections, Vaccines, and Other Physician-Administered Drugs

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| *Note:* | *For policy information regarding coverage of physician-administered drugs, see the Medical Policy Manual at indianamedicaid.com.* |

## Introduction

Physician-administered drugs include drugs that ordinarily cannot be self-administered, chemotherapy drugs, immunosuppressives, inhalation solutions, and other miscellaneous drugs and solutions. The Indiana Health Coverage Programs (IHCP) generally provides coverage for physician-administered drugs for medically necessary conditions, when provided in accordance with applicable policies and procedures.

The IHCP also provides coverage for many immunizations and vaccines. In addition, a variety of free vaccines are available for members 18 years of age and younger through the Vaccines for Children (VFC) program, administered through the Indiana State Department of Health (ISDH).

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| *Note:* | *For Healthy Indiana Plan (HIP), Hoosier Care Connect, and Hoosier Healthwise members, providers must contact the appropriate managed care entity (MCE) for specific policies and procedures. MCE contact information is included in the IHCP Quick Reference Guide available at indianamedicaid.com.* |

## National Drug Codes

Medication listed under *Section 510* of the *U.S. Federal Food, Drug, and Cosmetic Act* is assigned a unique 11-digit, three-segment number. This number, known as the National Drug Code (NDC), identifies the labeler or vendor, product, and package size. The first segment, known as the labeler code, is assigned by the Food and Drug Administration (FDA). A labeler is any firm that manufactures, repacks, or distributes a drug product. The second segment, known as the product code, identifies a specific drug, strength, and dosage form of that drug. The third segment, known as the package code, identifies the package size.

NDCs must be configured in what is referred to as a "5-4-2" format; the first segment must include five digits, the second segment must include four digits, the third segment must include two digits. If an NDC segment is missing a number on the product label, the appropriate number of zeros must be added at the beginning of the segment. For example, 12345-1234-12 is a correctly configured NDC. Because a zero can be a valid digit in the NDC, this can lead to confusion when trying to reformat the NDC back to its FDA standard. Example: 12345-0678-09 (11 digits) could appear as 12345-678-09 or 12345-0678-9 on the label, depending on the labeler's configuration. To ensure proper payment of claims, the NDC must be zero-padded as appropriate.

Procedure codes that require the submission of the product NDC are listed in *Procedure Codes That Require National Drug Codes* on the Code Sets page at indianamedicaid.com. This list is reviewed and updated on an annual basis or as determined by the Family and Social Services Administration (FSSA).

# Billing Procedure Codes That Require NDCs – Professional Claim Type

Providers must submit the product NDC, the NDC unit of measure (UOM), and NDC quantity of units, along with the procedure code and procedure code billing units, when submitting claims to the IHCP for all physician-administered drugs, except for vaccines. This requirement applies to drugs dispensed or administered in professional (medical) and institutional (facility) outpatient settings.

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| *Note:* | *Both procedure code billing units and NDC quantity are required. The procedure code billing units and NDC quantity do not always have a one-to-one relationship. The NDC quantity is based on the strength of the drug administered per unit, and the designated strength of the procedure code. The NDC quantity billed must reflect the procedure code quantity billed on the claim.* |

The *Federal Deficit Reduction Act of 2005* requires that NDCs are submitted in the appropriate fields of the professional claim (the *CMS-1500* claim form, the Provider Healthcare Portal professional claim, or the 837P electronic transaction). To report the NDC on the *CMS-1500* claim form, use the top-half shaded portion of fields 24A to 24H. Enter the following information, beginning at field 24A:

- Enter the NDC qualifier of N4.
- Enter the NDC 11-digit numeric code.
- Enter the drug description.
- Enter the NDC Unit qualifier:
  - F2 – International Unit
  - GR – Gram
  - ML – Milliliter
  - UN – Unit
- Enter the NDC Quantity (Administered Amount) in the format 9999.99.

Because the State may pay up to the 20% Medicare B copayment for dual-eligible individuals, the NDC is required on Medicare crossover claims for all applicable procedure codes.

## Billing Compounds with NDCs

When billing any compound drugs that require an NDC, providers must bill the appropriate NDC for each procedure code. Providers receive payment for all valid NDCs included in the compound drugs.

## Billing a Procedure Code with Multiple NDCs

When billing NDCs that have one procedure code but that involve multiple NDCs, providers bill the claim with the appropriate NDC for the drug they are dispensing or administering on separate detail lines. For example, if a provider administers 150 mg of Synagis, most likely a 50 mg vial plus a 100 mg vial would be used. These two vials have different NDCs but one procedure code; therefore, the item would be billed with two detail lines for the same procedure code and the corresponding NDCs. This process will be the same for crossover and Medicare Replacement plan claims.

## *Remittance Advice and NDC-Related Explanations of Benefits*

The Remittance Advice (RA) will not display the NDC submitted on the claim. The following explanations of benefits (EOBs) will be returned as a part of claim processing:

- EOB 217 – *NDC number is missing or not on file – an NDC number can be up to eleven numeric characters. For further information, see the pharmacy chapter in your provider manual. Please provide and resubmit.*
- EOB 810 – *NDC unit qualifier (unit of measure) is missing/invalid.*
- EOB 1016 – *This manufacturer does not participate in the drug rebate program.*
- EOB 4003 – *Less than effective drugs are not covered under Indiana Health Coverage Programs*.

> *Note: Less-than-effective drugs are drugs that the FDA approved before the Drug Amendments of 1962 (P.L. No. 87-781) and that FDA subsequently found to be less than effective.*

- EOB 4007 – *Noncovered NDC due to CMS termination – Claims with an NDC that has been terminated by the CMS will not be reimbursable*.
- EOB 4300 – *Invalid NDC to procedure code combination*.

> *Note: CMS maintains a Drug Manufacturer Contact Information list, which includes each drug company that participates in the Medicaid Drug Rebate Program. The list is available at the Medicaid Drug Rebate Program page at medicaid.gov. Providers can also contact their wholesaler or drug supplier to determine if products supplied are from CMS rebating labelers.*

# Billing and Reimbursement for Physician-Administered Drugs

With the exception of vaccines available through the VFC program, the IHCP calculates the maximum allowable amount for reimbursement for physician-administered drugs, using HCPCS codes and Current Procedural Terminology (CPT®[1]) immunization codes, on the basis of the most cost-effective, current reimbursement for an appropriate NDC, identified as the benchmark NDC. The maximum allowable reimbursement is equal to Wholesale Acquisition Cost (WAC) plus 5% (WAC+5%) of the benchmark NDC or, if no WAC data is available, CMS reimbursement, which is currently Average Sales Price (ASP) plus 6% (ASP+6%). The maximum allowable cost corresponds to the dose in the narrative description of the HCPCS or CPT code. When the procedure code specifies no dose in the narrative, the reimbursement rate is based on what corresponds to a typical dose for the particular code. The IHCP notifies providers through bulletins or banner pages about reimbursement rates for codes that have no dose or are dose-unspecified.

The IHCP reviews pricing for physician-administered drugs quarterly and updates pricing according to WAC data in the drug database file received from First DataBank. If no WAC data is available, Medicare's reimbursement, currently ASP+6%, is used.

For injectable drugs (excluding vaccines), providers may separately bill an appropriate CPT administration code, 96372 or 96373, in addition to the HCPCS or CPT drug code. If an evaluation and management (E/M) code is billed with the same date of service as a physician-administered drug, the provider should not bill a drug administration procedure code separately. Reimbursement for administration is included in the E/M code allowed amount. Separate reimbursement for drug administration is allowed when the administration is the only service billed by the practitioner. If more than one injection is given on the same

[1] *CPT copyright 2016 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association*

date of service and no E/M code is billed, providers may bill a separate administration fee for each injection using the appropriate codes. For information about billing and reimbursement for vaccines, see the *Vaccines* section of this document.

Under the fee-for-service reimbursement methodology, treatment room services are reimbursed at a flat rate that includes most drugs, injections, infusions, and supplies. See the *Treatment Rooms* section of the *Outpatient Hospital and Ambulatory Surgical Center Services* module, for more information.

For information about specific physician-administered contraceptive drugs, see the *Family Planning Services* module. For information about injections to prevent preterm delivery, see the *Obstetrical and Gynecological Services* module. For information about pharmacist-administered injections, see the *Pharmacy Services* module.

## Billing Nonspecific CPT or HCPCS Codes for Injections

When a provider cannot use an existing CPT or HCPCS code to bill for new injectable drugs that the IHCP covers, because the IHCP has not assigned a specific code, the provider should use an appropriate nonspecific CPT or HCPCS code such as J3490 – *Unclassified drugs*, J3590 – *Unclassified biologics*, or 90749 – *Unlisted vaccine/toxoid* to bill. Providers can use a nonspecific CPT or HCPCS code only when no code is available, and must include a narrative that accurately describes the drug being administered or the drug's route of administration.

The IHCP manually prices drugs billed with a nonspecific CPT or HCPCS code, and providers must submit them with an attachment. For all professional claims (*CMS-1500* claim form or electronic equivalent) billed with a nonspecific code, providers must include the NDC qualifier, NDC, NDC unit of measure, and number of units (quantity) administered on the claim itself; otherwise, the IHCP must deny the claim. The IHCP reimburses for nonspecific codes at the WAC+5% (or ASP+6% if no WAC data is available) of the NDC indicated on the claim, multiplied by the number of units administered.

## Joint Injections

The IHCP limits joint injections to four injections per joint site, per provider, per month. Claims submitted for more than three injections per joint site in a one-month period must have supporting documentation attached to indicate the medical necessity of the fourth injection per joint site. Additionally, providers billing for more than four joint injections per provider in a one-month period must have supporting documentation to indicate that the injections involve different joint sites and that no more than four injections were administered to a single joint.

## Vitamin B12 Injections

The IHCP limits vitamin B12 injections to one per 30 days per member.

## Botulinum Toxin

Currently, the FDA has approved four types of botulinum toxin injections: Botox (J0585), Dysport (J0586), Myobloc (J0587), and Xeomin (J0588). Providers should be aware that the potency units of these products are not interchangeable with each other; therefore, units of biological activity of one product cannot be compared to or converted into units of other botulinum toxin products.

Due to the short life of the botulinum toxin products, providers may bill the units injected in a single treatment ***and*** the units discarded and not used for another patient. The amount of the agent actually administered and the amount discarded should be documented in the patient's medical chart. If a vial is split between two or more members, the provider must bill the amount used for each member and then bill the unused amount as wastage on the claim for the last member injected.

For IHCP reimbursement, providers should bill botulinum toxin injections using the appropriate HCPCS code and must include one of the CPT codes available for billing chemodenervation. In addition, to ensure that the injections are medically necessary, IHCP reimbursement for botulinum toxin injections is limited to specific ICD diagnosis codes. Appropriate HCPCS, CPT, and ICD codes for botulinum toxin injections are listed in *Injections, Vaccines, and Other Physician-Administered Drugs Codes* on the *Code Sets* page at indianamedicaid.com.

The IHCP limits reimbursement of these injections to one treatment session every three months, per member, unless an additional injection is medically necessary. The medical record must contain documentation of the medical necessity for additional treatment sessions provided within a three-month period.

## Histrelin Implant (Supprelin LA)

Supprelin LA implant is approved by the FDA for the treatment of central precocious puberty (CPP). Children with CPP have an early onset of secondary sexual characteristics before age 8 in females and age 9 in males. They also show significantly advanced bone age that can result in diminished adult height attainment.

The workup for precocious puberty should include both physical and laboratory diagnostic confirmatory steps before treatment are initiated. Physical diagnostic documentation should include the following:

- A record of growth, Tanner stages, and height and weight percentiles
- External genitalia changes
- Abdominal, pelvic, neurologic examinations
- Signs of androgenization
- Other conditions such as McCune-Albright and hypothyroidism

Laboratory diagnostic studies include:

- Bone age x-rays
- Head MRI, ultrasonography of abdomen and pelvis
- FSH, LH, hCG assays
- Thyroid hydoxyprogesterone
- Inhibin levels
- GnRH testing

Supprelin LA is considered medically necessary when ***all*** the following criteria are met:

- The diagnosis of CPP is made before the age of 8 years in girls and 9 years in males.
- The diagnosis of CPP is documented in clinical records (history, physical findings, and laboratory analysis).
- A pediatric endocrinologist has been consulted and is in agreement with the diagnosis and treatment plan.

- The patient has a documented inability to tolerate leuprolide acetate (Lupron Depot Ped) intramuscularly (not due to pain) once every four weeks due to recurrent sterile fluid collections at the sites of injections.
- Documentation supports that subcutaneous injections of aqueous leuprolide, given once or twice daily (total dose 60 mg/kg/24 hr) or intranasal administration of the GnRH agonist nafarelin (Synarel) 800 mg bid would not be tolerated or complied with.

This service does not require PA.

Supprelin LA implant is designed to deliver approximately 65 mcg of histrelin per day over 12 months. The recommended dose of histrelin is one 50 mg implant inserted subcutaneously for 12 months. The implant must be removed 12 months after insertion. At the time the implant is removed, another implant may be inserted to continue therapy. The HCPCS procedure code for Supprelin LA is J9226 – *Histrelin implant (Supprelin LA), 50 mg*.

Supprelin LA is reimbursed only when billed with the ICD-10 diagnosis code E30.1 – *Precocious puberty*.

## *Histrelin Implant (Vantas)*

The IHCP reimburses providers for HCPCS code J9225 – *Histrelin implant (Vantas)* only when billed with the ICD-10 diagnosis code C61 – *Malignant neoplasm of prostate* or Z85.46 – *Personal history of malignant neoplasm of prostate*.

The IHCP considers J9225 medically necessary for the palliative treatment of advanced prostate cancer when ***all*** the following criteria are met:

- A medical need for the implant (such as mobility or compliance issues, or inability to receive daily injections) is determined.
- A documented diagnosis of cancer of the prostate is made.
- A demonstrated response to luteinizing hormone-releasing hormone (LHRH) agonists is confirmed by periodic measurement of testosterone and prostate-specific antigen (PSA) levels.
- The member has a life expectancy of more than one year.
- The member has not had a bilateral orchiectomy.

The IHCP does not reimburse for J9225 if a member is hypersensitive to gonadotropin releasing hormone (GnRH), GnRH analogs, or any of the components of Vantas.

Vantas is designed to deliver approximately 50 mcg histrelin per day over 12 months. The recommended dose of histrelin is one 50 mg implant inserted subcutaneously for 12 months. The implant must be removed 12 months after insertion. At the time the implant is removed, another implant may be inserted to continue therapy. J9225 is limited to one unit per member per 12 months and is limited to males. Prior authorization is not required for this service.

# Vaccines

For vaccines (excluding VFC vaccines), providers may separately bill an appropriate CPT administration code, 90471–90474, in addition to the CPT drug code. If an E/M code is billed with the same date of service as a physician-administered drug, the provider should not bill a drug administration procedure code separately. Reimbursement for administration is included in the E/M-code-allowed amount**. Separate reimbursement for drug administration is allowed when the administration is the only service billed by the practitioner.** If more than one injection is given on the same date of service and no E/M code is billed, providers may bill a separate administration fee for each injection using the appropriate codes.

See the *Pharmacy Services* module for information regarding reimbursement to pharmacy providers for pharmacist-administered vaccines.

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| *Note:* | *FQHC- and RHC-specific encounter rates already include payment for immunizations and administration.* |

## Children and Hoosiers Immunization Registry Program

The Children and Hoosiers Immunization Registry Program (CHIRP) is a secure, web-based application administered by the ISDH. An immunization registry program is designed to permanently store a person's immunization records in an electronic format.

Healthcare providers can use the registry to both review vaccination records for their patients and record all newly administered vaccinations. The state of Indiana mandates use of the registry for certain providers.

*Indiana Code IC 16-38-5-2* mandates that all medical providers in the state of Indiana submit complete vaccination records to the state CHIRP registry system within seven business days. This legislation covers all vaccines that are administered to individuals under 19 years of age.

For more information about CHIRP, contact the CHIRP helpdesk at 1-888-227-4439 or chirp@isdh.in.gov.

## Reporting Individual Cases of Vaccine Preventable Diseases

Suspected and confirmed cases of most vaccine preventable diseases are reportable to the ISDH using the *Confidential Report of Communicable Diseases* form available at in.gov/isdh. The form includes a complete list of reportable diseases and conditions.

The complete revised Communicable Disease Control Rule is available at in.gov.

## Vaccines for Children Program

Vaccines for Children (VFC) is a federal program that provides vaccines at no cost to children who might not otherwise be vaccinated because of inability to pay. Children who are eligible for VFC are entitled to receive all vaccines recommended by the Advisory Committee on Immunization Practices (ACIP). These vaccines protect babies, young children, and adolescents from 16 different diseases. The ISDH administers the VFC program in Indiana.

Procedure codes for VFC-available vaccines, along with common brand names, are available in *Injections, Vaccines, and Other Physician-Administered Drugs Codes* on the *Code Sets* page at indianamedicaid.com.

Direct questions concerning VFC provider enrollment, patient eligibility for VFC, and vaccine orders and distribution to the ISDH at:

**Indiana Immunization Program**
**Indiana State Department of Health**
**2 North Meridian Street**
**Indianapolis, IN 46204**
**Telephone: (317) 233-7704 or 1-800-701-0704**
**Fax: (317) 233-3719**

Contact IHCP Customer Assistance toll-free at 1-800-457-4584 with questions about IHCP fee-for-service (FFS) billing and reimbursement for VFC vaccines. Contact the patient's MCE with questions about VFC vaccine administration and reimbursement under the managed care network.

See the Centers for Disease Control (CDC) Vaccine Price List at cdc.gov for information on what vaccines are covered under the VFC program. In addition, providers can refer to the *Vaccines for Children* page at in.gov/isdh for information regarding vaccine availability and general program information.

## Provider Enrollment in the VFC Program

The ISDH Immunization Program handles VFC provider enrollment and education as well as VFC vaccine orders and distribution. To participate in the VFC program, providers should complete the following steps:

1. Contact the ISDH and request VFC provider enrollment forms.
2. Complete and mail the provider enrollment forms.
3. Receive appropriate training and technical assistance.
4. Order vaccines periodically, as needed, and maintain appropriate vaccine supply records.

## VFC Eligibility and Tracking

The goal of the VFC program is to help raise childhood immunization levels in the United States by supplying healthcare providers with free vaccine to administer to children 18 years old and under who meet one or more of the following criteria:

- Enrolled in Medicaid
- Without health insurance
- Identified by parent or guardian as American Indian or Alaskan native
- Underinsured, for example, children with health insurance that does not cover immunizations

Underinsured patients who have health insurance that does not cover immunizations are eligible to receive VFC vaccines at a federally qualified health center (FQHC) or rural health clinic (RHC). See the *Federally Qualified Health Centers and Rural Health Clinics* module for more information. Other VFC providers may be able to vaccinate underinsured children. Contact the ISDH Immunization Division for more information.

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| *Note:* | *The FSSA, the Children's Health Insurance Program (CHIP), and ISDH worked together to open the VFC program to children in all of the IHCP Medicaid, Hoosier Care Connect, and Hoosier Healthwise benefit packages.* |

To screen patients for VFC eligibility, providers may use the *Patient Eligibility Screening Record* form. This form includes a box to indicate whether children are eligible for any form of Medicaid. Providers may use this form or may incorporate it into existing clinical forms.

See *VFC Provider Documents* at in.gov/isdh for all VFC forms.

## IHCP Reimbursement for VFC Vaccine Administration

IHCP reimbursement for vaccines available through the VFC program is limited to the VFC vaccine administration fee. The VFC vaccine administration fee is a maximum of $8 (payment is made at the lower charge of $8 or the submitted charge).

Providers using VFC-provided vaccines should bill the IHCP for the VFC vaccine administration fee by billing:

- Z00.121 or Z00.129 as the primary diagnosis code
- Procedure code of the specific vaccine administered with a billed amount of $0.00

- Appropriate vaccine administration code with the SL modifier:
  - 90471 SL − Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); 1 vaccine (single or combination vaccine/toxoid); VFC vaccine administration
  - 90472 SL − Each additional vaccine (single or combination vaccine/toxoid); VFC vaccine administration
  - 90473 SL − Immunization administration by intranasal or oral route; 1 vaccine (single or combination vaccine/toxoid); VFC vaccine administration
  - 90474 SL − Each additional vaccine by intranasal or oral route (single or combination vaccine/toxoid); VFC vaccine administration

When a VFC vaccine is administered by a nurse practitioner employed by physicians in a physician-directed group or clinic, the previous codes should be billed followed by the SA modifier (for example, 90471 SL SA) to identify the service is performed by a nurse practitioner.

For combined vaccines, bill the correct code for the combined vaccine and charge only one vaccine administration fee.

The allowed amount for each administration of a VFC vaccine is $8. Providers are reminded that reimbursement for a VFC vaccine itself is not appropriate, because providers receive VFC vaccines at no charge. However, to ensure that the vaccine is appropriately included in CHIRP, the provider must bill the appropriate CPT code for the vaccine and a billed amount of $0.00.

### Third Party Liability

For vaccines administered to VFC-eligible children, providers can bill directly to the appropriate IHCP claim-processing unit (Hewlett Packard Enterprise for fee-for-service claims or the member's MCE for managed care claims) when the primary diagnosis is Z00.121. Providers need not bill these vaccines to the primary insurance company before billing the IHCP. Providers should not experience third-party liability (TPL) claim denials for children enrolled in Hoosier Healthwise Package C. If providers obtain information that identifies a primary insurance for children enrolled in Hoosier Healthwise Package C, they should contact the Hewlett Packard Enterprise TPL Unit at 1-800-457-4584.

## *Billing for Privately Purchased Vaccines*

To guarantee that all IHCP children receive immunizations as needed, providers should bill according to the source of the vaccine stock. For vaccines that are not part of the VFC program – or for vaccines that are typically part of the VFC program, but have been purchased or supplied out of private stock – providers may bill for both the vaccine and its administration (using CPT code 90471, 90472, 90473, or 90474). However, if an E/M service code is billed with the same date of service as an office-administered immunization, providers should not bill the vaccine administration code separately. **Reimbursement for the administration is included in the E/M code-allowed amount**. Separate reimbursement is allowed only when the administration of the drug is the only service billed by the practitioner. In addition, if more than one vaccine is administered on the same date of service and no E/M code is billed, providers may bill an administration fee for each injection.

The IHCP maximum fee information is on the Fee Schedule at indianamedicaid.com. Be aware of the member's primary medical provider assignment, managed care delivery system assignment, and third-party liability resources.

Providers must continue to submit claims to the appropriate claim-processing unit (Hewlett Packard Enterprise or the member's managed care entity) for each member, regardless of the source of the vaccine stock. Claims are eligible for postpayment review, and providers must maintain documentation and invoices related to private stock when substituting for VFC vaccine.