INDIANA HEALTH COVERAGE PROGRAMS

PROVIDER REFERENCE MODULE

Injections, Vaccines and Other Physician-Administered Drugs

LIBRARY REFERENCE NUMBER: PROMOD00034
PUBLISHED: OCT. 19, 2021
POLICIES AND PROCEDURES AS OF JULY 1, 2021
VERSION: 6.0

Revision History

Version	Date	Reason for Revisions	Completed By
1.0	Policies and procedures as of Oct. 1, 2015 Published: Feb. 25, 2016	New document	FSSA and HPE
1.1	Policies and procedures as of April 1, 2016 Published: July 28, 2016	Scheduled update	FSSA and HPE
1.1	Policies and procedures as of April 1, 2016 (*Core*MMIS updates as of Feb. 13, 2017) Published: March 28, 2017	*Core*MMIS update	FSSA and HPE
2.0	Policies and procedures as of May 1, 2017 Published: Aug. 24, 2017	Scheduled update	FSSA and DXC
3.0	Policies and procedures as of May 1, 2018 Published: Aug. 16, 2018	Scheduled update	FSSA and DXC
3.0	Policies and procedures as of May 1, 2018 Published: Aug. 24, 2018	Addition of code table reference	FSSA and DXC
4.0	Policies and procedures as of July 1, 2019 Published: Jan. 30, 2020	Scheduled update	FSSA and DXC
5.0	Policies and procedures as of July 1, 2020 Published: Sept. 17, 2020	Scheduled update	FSSA and DXC
6.0	Policies and procedures as of July 1, 2021 Published: Oct. 19, 2021	Scheduled update: • Edited text as needed for clarity • Changed ISDH references to IDOH • Changed DXC references to Gainwell • Updated the *Managed Care Carve-Outs* section to add an exception for Zolgensma and a note about COVID-19 vaccination • In the *Drug Administration Fees* section: – Added a note about COVID-19 administration codes	FSSA and Gainwell

Version	Date	Reason for Revisions	Completed By
		– Added a note about the limit prohibiting reimbursement of both a drug administration code and a treatment room revenue code for the same date of service as being per provider • Added the *Brexanolone (Zulresso)* section • Added J5070 to the *Buprenorphine* section • Added the *Casimersen (Amondys 45)* section • Added the *Crizanlizumab-tmca (Adakveo)* section • Added the *Eptinezumab-jjmr (Vyepti)* section • Added the *Leuprolide Acetate (Fensolvi)* section • Added noncovered treatments to the *Nusinersen (Spinraza)* section • Updated the *Onasemnogene Abeparvovec-xioi (Zolgensma)* section	

Table of Contents

Injections, Vaccines and Other Physician-Administered Drugs

> *Note: The information in this module applies to Indiana Health Coverage Programs (IHCP) services provided under the **fee-for-service (FFS)** delivery system. For information about services provided through the **managed care** delivery system – including Healthy Indiana Plan (HIP), Hoosier Care Connect or Hoosier Healthwise services – providers must contact the member's managed care entity (MCE) or refer to the MCE provider manual. MCE contact information is included in the IHCP Quick Reference Guide at in.gov/medicaid/providers.*
>
> *For updates to information in this module, see IHCP Banner Pages and Bulletins at in.gov/medicaid/providers.*

Introduction

Physician-administered drugs include drugs that ordinarily cannot be self-administered, chemotherapy drugs, immunosuppressives, inhalation solutions, and other miscellaneous drugs and solutions. These drugs may be administered by a physician or by another qualified medical practitioner, such as a physician assistant or nurse practitioner. For information about *pharmacist*-administered drugs and vaccines, see the *Pharmacy Services* module.

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, various free vaccines are available for members 18 years of age and younger through the Vaccines for Children (VFC) program, administered through the Indiana Department of Health (IDOH).

National Drug Code Requirements

Medication listed under *Section 510* of the *U.S. Federal Food, Drug, and Cosmetic Act* is assigned a unique number known as the National Drug Code (NDC). The NDC contains three segments:

- 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.

In accordance with the *Federal Deficit Reduction Act of 2005*, providers must submit the NDC along with the Healthcare Common Procedure Coding System (HCPCS) procedure code when billing claims to the IHCP for most physician-administered drugs, excluding vaccines. Applicable HCPCS codes are listed in *Procedure Codes That Require National Drug Codes*, accessible from the *Code Sets* page at in.gov/medicaid/providers. This list is reviewed and updated on an annual basis or as determined by the Family and Social Services Administration (FSSA).

In addition to the NDC number itself, providers must also submit the NDC unit of measure (UOM) and NDC quantity of units.

> *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 units billed on the claim.*

This requirement applies to both professional claims and outpatient institutional claims. Because the IHCP may pay up to the 20% Medicare B copayment for dually eligible individuals, the NDC is also required on Medicare crossover claims for all applicable procedure codes.

Entering NDC Information on Claims

For billing purposes, the NDC must be configured as 11 digits, using 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 the product label displays an NDC with fewer than 11 digits, a zero must be added at the beginning of the appropriate segment to achieve the 5-4-2 format. Hyphens and spaces are omitted when submitting the NDC number on a claim. For example, if a package displays an NDC as 12345-1234-1, a zero must be added to the beginning of the third segment to create an 11-digit NDC as follows: 12345123401.

The NDC information must be entered in the appropriate fields of the professional claim (*CMS-1500* claim form, IHCP Provider Healthcare Portal (Portal) professional claim or 837P electronic transaction) or the outpatient institutional claim (*UB-04* claim form, Portal institutional claim or 837I electronic transaction).

On the *CMS-1500* claim form, enter the NDC information in the shaded, top-half portion of each applicable detail line, beginning at field 24A. On the *UB-04* claim form, enter the NDC information in field 43 for each detail line with an applicable HCPCS code (in field 44).

Enter the information on the **paper** claim form as follows:

1. Enter the NDC qualifier of **N4**.
2. Enter the 11-digit numeric NDC (without spaces or hyphens).
3. Enter the drug description.
4. Enter the appropriate NDC unit-of-measure qualifier:
   - F2 – International Unit
   - GR – Gram
   - ME – Milligram
   - ML – Milliliter
   - UN – Unit
5. Enter the NDC quantity (administered amount) in the format 9999.999.

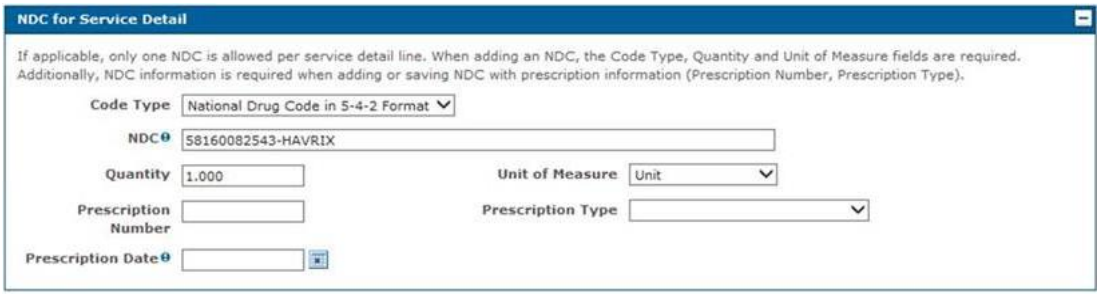
For professional and institutional outpatient claims submitted via the **Portal**, report NDC information in the *NDC for Service Detail* panel (see Figure 1) for the appropriate service detail, as follows:

1. Select "National Drug Code in 5-4-2 Format" from the Code Type drop-down list.

   Selecting this option is equivalent to entering the NDC qualifier of **N4** on the paper claim form. No other options are available for this field.
2. Enter the 11-digit NDC (without hyphens or spaces) in the NDC field.
3. The Portal autofills a drug description for the NDC entered.

4. Enter the NDC quantity, with up to three decimal places, in the Quantity field.
5. Select the appropriate option from the Unit of Measure drop-down list:
   - International Unit
   - Gram
   - Milligram
   - Milliliter
   - Unit

Figure 1 – Entering NDC information in the Portal



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 drug.

Billing a Procedure Code with Multiple NDCs

When billing a single procedure code that involves multiple NDCs, providers bill the claim with each appropriate NDC for the drug they are dispensing or administering on a separate detail line, repeating the HCPCS code as needed for each unique NDC code.

For example, a 50 mg vial and a 100 mg vial of Synagis have different NDCs but the same procedure code. Therefore, if a provider administers 150 mg of Synagis using these two vials, the item would be billed with two detail lines for the same procedure code, and the appropriate NDC would be entered on each line.

NDC-Related Explanations of Benefits

The Remittance Advice (RA) does not display the NDC submitted on the claim. However, the following NDC-related explanations of benefits (EOBs) may be returned as a part of claim processing:

- EOB 0217 – *NDC number is missing or not on file – an NDC number can be up to eleven numeric characters. See the pharmacy chapter in your provider manual. Please provide and resubmit.*
- EOB 0810 – *NDC unit qualifier (unit of measure) is missing/invalid.*
- EOB 1016 – *This manufacturer does not participate in the drug rebate program.*

> *Note: The Centers for Medicare & Medicaid Services (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.*

- 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*.

340B Program Requirements

Section 340B of the *Public Health Service Act* limits the cost of covered outpatient drugs to entities such as certain federal grantees, FQHCs, FQHC look-alikes and qualified disproportionate share hospitals, enabling these entities to purchase drugs at discounted rates and stretch scarce federal resources.

This program applies to clinic-administered drugs within eligible facilities. Vaccines and inpatient drugs are not included. If the entity wishes to serve Medicaid members using 340B stock, it must dispense only 340B stock drugs. Also, the entity can bill the Medicaid program only the actual acquisition cost for the drug.

Providers enrolled in the 340B program should use one of the following modifiers when billing for 340B drugs on professional claims (*CMS-1500* claim form, Portal professional claim or 837P electronic transaction) or institutional claims (*UB-04* claim form, Portal institutional claim or 837I electronic transaction):

- JG – *Drug or biological acquired with 340B drug pricing program discount*
- TB – *Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes*

> *Note: Providers should refer to the Billing Instructions for 340B-Aquired Drugs section of the January 2018 Update of the Hospital Outpatient Prospective Payment System (OPPS) and to the CMS 340B Modifier FAQs on the CMS website at cms.gov for information regarding the proper use of modifiers **JG** and **TB**. Although these two CMS publications are specific to Medicare, IHCP guidance for FFS claims regarding 340B drugs follows Medicare guidelines.*

Reimbursement for Physician-Administered Drugs

With the exception of vaccines available through the VFC program and certain manually priced drugs, the IHCP calculates the maximum allowable amount for reimbursement for physician-administered drugs (billed using HCPCS drug codes) and vaccines (billed with Current Procedural Terminology [CPT®[1]] vaccine 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.

[1] *CPT copyright 2021 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association.*

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.

> *Note: For outpatient facility billing under the fee-for-service reimbursement methodology,* ***treatment room services*** *are reimbursed at a flat rate that includes most drugs, injections and supplies. See the Treatment Room Visits section of the Outpatient Facility Services module for details.*
>
> *For inpatient hospital stays, all drugs, injections and supplies are included in the diagnosis-related group (DRG) payment, with the exception of specific drugs as described in the Hospital Reimbursement for Physician-Administered Drugs section.*

Nonspecific CPT or HCPCS Drug Codes

When a provider cannot use an existing CPT or HCPCS code to bill for new drugs that the IHCP covers because the IHCP has not assigned a specific code, the provider should bill using an appropriate nonspecific CPT or HCPCS code, such as the following:

- J3490 – *Unclassified drugs*
- J3590 – *Unclassified biologics*
- 90749 – *Unlisted vaccine/toxoid*

Providers can use a nonspecific CPT or HCPCS code only when no code is available. Providers 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 nonspecific, nonvaccine HCPCS codes (such as J3490 and J3590) based on the NDC billed. All professional and institutional claims billed with a nonspecific, nonvaccine drug code must include the following information:

- NDC qualifier
- NDC
- Drug description
- NDC unit of measure
- Number of units (quantity) administered

If the required information is not included on the claim, the IHCP will deny the claim.

The IHCP reimburses for nonspecific, nonvaccine drug 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.

Hospital Reimbursement for Physician-Administered Drugs

The IHCP allows separate reimbursement, outside the diagnosis-related group (DRG) payment, for certain drugs administered during an inpatient hospital stay. To receive separate reimbursement, the drugs must be billed as **professional** claims (using the *CMS-1500* claim form or electronic equivalent). For applicable codes, see *Physician-Administered Drugs Carved Out of Managed Care and Reimbursable Outside the Inpatient Diagnosis-Related Group*, accessible from the Code Sets page at in.gov/medicaid/providers.

Managed Care Carve-Outs

Certain physician-administered drugs are carved out from the managed care delivery system. The IHCP processes prior authorization requests and claims for these designated physician-administered drugs through the fee-for-service (FFS) delivery system for *all* IHCP members, including members enrolled in Healthy Indiana Plan (HIP), Hoosier Care Connect and Hoosier Healthwise managed care programs.

For a list of applicable drugs, see *Physician-Administered Drugs Carved Out of Managed Care and Reimbursable Outside the Inpatient Diagnosis-Related Group*, accessible from the *Code Sets* page at in.gov/medicaid/providers.

Prior authorization requests and claims for these carved-out physician-administered drugs must be submitted as follows for all IHCP members:

- Any required prior authorization requests (except requests for Zolgensma) must be submitted to Gainwell Technologies. (PA requests for Zolgensma must be emailed to the FSSA as described in the *Onasemnogene Abeparvovec-xioi (Zolgensma)* section.)
- All claims must be submitted to Gainwell Technologies. The claims must be billed using the professional claim (*CMS-1500* claim form or electronic equivalent).

To clarify, only the drug procedure codes indicated on the table are carved out of managed care. All services associated with the drug (for example, laboratory testing, administration of the drug, inpatient stay during which the drug is administered) are the responsibility of the managed care entity (MCE) with which the member is enrolled. Physician-administered drugs that are not carved out of managed care per IHCP policy remain the responsibility of the MCE with which the managed care member is enrolled.

> *Note: Coronavirus disease 2019 (COVID-19) vaccination is carved out of managed care benefits. Both the drug and its administration should be billed to Gainwell for all members, including those in managed care programs. COVID-19 vaccines are to be supplied free of charge, without copay, to all IHCP members, including members in limited benefit categories.*

Drug Administration Fees

The IHCP may provide separate reimbursement for the administration of a drug when billed with the appropriate procedure code:

- Nonvaccine injections: 96372–96375
- Vaccine administration: 90471–90474

> *Note: COVID-19 vaccine administration codes 0001A, 0002A, 0011A, 0012A, 0031A and M0201 are also reimbursable.*

However, 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 on that date of service.** 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.

> *Note: For VFC vaccines, the IHCP reimburses **only** for the administration of the vaccine, not for the vaccine itself. The administration of a VFC vaccine is separately reimbursable in addition to an E/M service. For details, including specific billing instructions, see the Vaccines for Children Program section.*

For drugs administered in an outpatient facility setting, the IHCP will not reimburse for an administration procedure code billed for the same date of service as a treatment room revenue code if the revenue code was already reimbursed for that date of service. The reverse also applies; the IHCP will not reimburse a treatment room revenue code billed for the same date of service as an injection administration procedure code that was already paid. This limit includes codes billed on the same or different claims, and by the same or different providers.

> *Note: Effective Aug. 27, 2021, and applying retroactively to outpatient claims with dates of service on or after Oct. 31, 2019, this reimbursement limit will be "per provider." The limit will apply to drug-administration procedure codes and treatment room revenue codes billed for the same date of service, on the same or different claims and* ***by the same provider****.*

For drugs administered during an inpatient stay, there is no separate reimbursement for the administration of the drug – including in cases where the drug itself is eligible for separate reimbursement, as described in the *Hospital Reimbursement for Physician-Administered Drugs* section.

Vaccines

Providers should bill vaccination services according to the source of the vaccine stock – privately purchased or obtained through the Vaccines for Children (VFC) program – as described in the following sections.

For children under the age of 19, if a vaccine is available through the VFC program, the IHCP will not provide reimbursement for a non-VFC vaccine (referred to as private stock vaccine). To guarantee that all IHCP children receive immunizations as needed, providers are encouraged to enroll in the VFC program if they are not currently enrolled.

Providers must continue to submit claims to the appropriate claim-processing unit (Gainwell for fee-for-service, nonpharmacy claims or the member's MCE for managed care claims), regardless of the source of the vaccine stock. See the *Pharmacy Services* module for information regarding reimbursement to pharmacy providers for pharmacist-administered vaccines.

> *Note: FQHC- and RHC-specific encounter rates already include payment for vaccines and their administration.*

Billing for Privately Purchased Vaccines

For IHCP-covered vaccines that are **not** part of the VFC program, and for all covered vaccines administered to adults aged 19 years and older, providers may receive reimbursement for the vaccine itself as well as for its administration, as described in the *Drug Administration Fees* section.

> *Note: See the Third-Party Liability section for information about the option to bill the IHCP as a secondary insurer for the administration of a privately purchased vaccine for a VCF member.*

The IHCP maximum fee information is on the Professional Fee Schedule, accessible from the *IHCP Fee Schedules* page at in.gov/medicaid/providers. Be aware of the member's primary medical provider assignment, managed care delivery system assignment and third-party liability resources. Claims are eligible for postpayment review, and providers must maintain documentation and invoices related to private stock.

Vaccines for Children Program

Vaccines for Children (VFC) is a federally funded program that provides vaccines at no cost to providers for children under 19 years of age 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). 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: Information for Providers* page at in.gov/health for information regarding vaccine availability, provider obligations and general program information.

The IDOH administers the VFC program in Indiana. All VFC vaccine ordering, distribution and accountability processes are administered through the IDOH Immunization Division. Providers can direct questions concerning VFC provider enrollment, patient eligibility for VFC, and vaccine orders and distribution to the IDOH at:

Indiana Department of Health
Immunization Division
2 N. Meridian St.
Indianapolis, IN 46204

Telephone: 800-701-0704
Email: immunize@isdh.in.gov

Provider Enrollment in the VFC Program

The federal VFC program includes private and public practitioners across Indiana. The IDOH Immunization Division handles VFC provider enrollment and education as well as VFC vaccine orders and distribution. To enroll in the VFC program, providers should complete the following steps:

1. Review the IDOH VFC program eligibility statements to ensure that your practice is able to meet all program requirements:
   – Provider Eligibility for Publicly Funded Vaccine Programs
   – Childhood Vaccine Eligibility Statement
2. Download the *Immunization Provider Contact Request Form*, accessible from the Document Center at in.gov/health.
3. Complete the form and submit it to the IDOH in one of the following ways:
   – Email to enrollments@isdh.in.gov
   – Fax to 317-233-3719

A representative from the IDOH Immunization Division will contact the provider within five business days after receiving the form to help complete the necessary enrollment paperwork and schedule a time to visit the provider's location.

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 vaccines to administer to children 18 years old and younger who meet one or more of the following criteria:

- Enrolled in Medicaid (including children enrolled in Hoosier Healthwise Package C)
- 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

> *Note: The FSSA, the Children's Health Insurance Program (CHIP) and IDOH worked together to open the VFC program to children in all 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.

IHCP Reimbursement for VFC Vaccine Administration

IHCP reimbursement for vaccines supplied through the VFC program is limited to the VFC vaccine administration fee. The VFC vaccine administration fee is a maximum of $15 (payment is made at whichever is lower – $15 or the submitted charge).

Providers using VFC-provided vaccines should bill the IHCP for the VFC vaccine administration fee by submitting the claim as follows:

- Appropriate diagnosis code in the primary position (and indicated with the diagnosis pointer for the vaccine and administration procedure codes)
  - Z00.121 – *Encounter for routine child health examination with abnormal findings*
  - Z00.129 – *Encounter for routine child health examination without abnormal findings*
- Procedure code of the specific vaccine administered with a billed amount of $0.00
- Appropriate vaccine **administration procedure 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*

> *Note: For a VFC vaccine administered during the course of an office visit, providers may bill the VFC vaccine administration procedure code/modifier combination in addition to the evaluation and management (E/M) procedure code.*

When a VFC vaccine is administered by a nurse practitioner employed by physicians in a physician-directed group or clinic, the administration procedure 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 $15.

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.

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

Third-Party Liability

When VFC vaccine is administered to a child enrolled in Medicaid, and the primary diagnosis is Z00.121 or Z00.129, providers can bill directly to the appropriate IHCP claim-processing unit (Gainwell for fee-for-service claims or the member's MCE for managed care claims) for reimbursement of the administration fee. Providers need not bill the administration fee to the primary insurance company before billing the IHCP. However, after a claim is submitted, the IHCP may seek reimbursement for the administration fee from the primary insurer.

> *Note: 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 IHCP TPL Unit at 800-457-4584.*

Children and Hoosier Immunization Registry Program

The Children and Hoosier Immunization Registry Program (CHIRP) is a secure, web-based application administered by the IDOH. 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 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 IDOH using the *Confidential Report of Communicable Diseases* form (State Form 43823) available on the IDOH *Forms* page at in.gov/health. The form includes a complete list of reportable diseases and conditions.

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

Coverage and Limitations for Specific Physician-Administered Drugs

The IHCP generally provides coverage for all physician-administered drugs for medically necessary conditions. However, reimbursement is not available to a practitioner for injecting medications that can be self-administered, unless justified by the patient's condition. Possible noncompliance by a recipient to oral medications is insufficient justification to administer injections.

It is the provider's responsibility to ensure the treatment is appropriate based on FDA-approved indications, peer-reviewed journals and standards of practice. The IHCP reserves the right to place diagnosis restrictions on physician-administered drugs when deemed appropriate.

The following sections provide coverage and limitations for certain types of physician-administered drugs and injections. Other modules may include information about physician-administered drugs or injections related to particular types of services or providers. For example, for information about specific physician-administered ophthalmological drugs, see the *Vision Services* module. For information about physician-administered oncology drugs, see the *Oncology 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.

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

Treatment with botulinum toxin injections provides temporary relief of symptoms and is indicated for use when conventional treatment has failed or in conjunction with physical therapy or other therapeutic techniques. The IHCP provides reimbursement for chemodenervation using botulinum toxins for treating certain neuromuscular conditions, including cervical dystonia, cerebral palsy, multiple sclerosis and other muscular and neurological conditions that cause excessive muscle contractions. The IHCP does not provide reimbursement for botulinum toxins for cosmetic purposes.

Currently, the FDA has approved four types of botulinum toxin injections. 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 International Classification of Diseases (ICD) diagnosis codes. Appropriate HCPCS, CPT and ICD codes for botulinum toxin injections are listed in *Injections, Vaccines and Other Physician-Administered Drugs Codes*, accessible from the *Code Sets* page at in.gov/medicaid/providers.

The IHCP limits reimbursement of these injections to one injection 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.

Brexanolone (Zulresso)

Effective for dates of service on or after Oct. 1, 2020, the IHCP covers J1632 – *Injection, brexanolone, 1 mg*. Prior authorization is required. The following medical necessity criteria must be met:

- Member must have diagnosis of postpartum depression.
- Provide confirmation that member, pharmacy and facility are enrolled in the Zulresso REMS program.
- Must provide name and NPI of the qualified facility and healthcare providers providing and monitoring infusion

Buprenorphine

The buprenorphine *drug* is covered by the IHCP, but there is no separate code for *administering* the drug. Physician-administered versions of the buprenorphine drug are billed using the following procedure codes:

- J0570 – *Buprenorphine implant, 74.2 mg*
- J0571 – *Buprenorphine, oral, 1 mg*
- J0572 – *Buprenorphine/naloxone, oral, less than or equal to 3 mg buprenorphine*
- J0573 – *Buprenorphine/naloxone, oral, greater than 3 mg, but less than or equal to 6 mg buprenorphine*
- J0574 – *Buprenorphine/naloxone, oral, greater than 6 mg, but less than or equal to 10 mg buprenorphine*
- J0575 – *Buprenorphine/naloxone, oral, greater than 10 mg buprenorphine*
- J0592 – *Injection, buprenorphine HCl, 0.1 mg*

Procedure code J0592 is not separately reimbursable to facilities.

Reimbursement for these codes is limited to certain IHCP provider specialties. The list of eligible specialties is being added to the *Mental Health and Addiction Services* module.

Buprenorphine Extended-Release (Sublocade)

IHCP coverage of buprenorphine extended-release (Sublocade) requires PA. This agent may be considered medically necessary when ***all*** the following criteria are met:

- Member is 18 years of age or older.
- Member has initiated opioid use disorder treatment on a transmucosal buprenorphine-containing product delivering the equivalent of 8 mg to 24 mg buprenorphine daily, for a minimum of seven days.
- Physician meets all qualifications (federal, state and local) to prescribe buprenorphine/naloxone or buprenorphine.
- Member has a diagnosis of opiate dependence/addiction (at prescriber's office or verified from prior rehab/detox).
- Physician must verify that the risks of using buprenorphine with alcohol or benzodiazepines have been explained to the member.
- Physician must verify that there are no untreated or unstable psychiatric conditions that would interfere with buprenorphine/naloxone or buprenorphine compliance.
- If the member is pregnant, the physician must verify one of the following:
  - The choice of buprenorphine injection over alternatives has been explained to the member.
  - Documentation supporting that the member is unable to use an alternative medication was submitted to the obstetrician's office.
- Physician must provide documentation of the member's referral to or active involvement in formal counseling with a licensed behavioral health provider. The name of the behavioral health provider and where the member is receiving counseling must be indicated.
- Dose of Sublocade is less than or equal to 300 mg per month.

Sublocade is billed using the following procedure codes:

- Q9991 – *Injection, buprenorphine extended-release (Sublocade), less than or equal to 100 mg*
- Q9992 – *Injection, buprenorphine extended-release (Sublocade), greater than 100 mg*

Casimersen (Amondys 45)

Effective for dates of service on or after July 1, 2021, the IHCP covers casimersen (Amondys 45), billed with HCPCS code C9075 – *Injection, casimersen, 10 mg*.

> *Note: Effective for dates of service on or after Oct. 1, 2021, Amondys 45 should be billed with HCPCS code J1426 instead of C9075.*

Prior authorization is required. The following medical necessity criteria must be met:

- The member must have a diagnosis of Duchenne muscular dystrophy (DMD), with confirmed mutation of the DMD gene that is amenable to exon 45 skipping.
- The dosage is 30 mg/kg once weekly; patient weight must be provided to confirm dose.
- The prescriber must provide documentation of current clinical status (for example, Brooke Score, six-minute walk test, and so on) to compare upon reevaluations of therapy.

Amondys 45 is not used concomitantly with other exon-skipping therapies for DMD.

Crizanlizumab-tmca (Adakveo)

The IHCP covers HCPCS code J0791 – *Injection, crizanlizumab-tmca, 5 mg*.

Prior authorization is required. For dates of service on or after May 4, 2021, the following medical necessity criteria must be met:

- Member must be 16 years or older.
- Diagnosis is made of a sickle cell disease, including but not limited to homozygous hemoglobin S, sickle hemoglobin C disease, sickle beta 0 thalassemia and sickle beta + thalassemia.
- Member is currently receiving hydroxyurea therapy; or member has a history of intolerance or contraindication to hydroxyurea therapy.
- One of the following has occurred:
  - Individual has experienced a sickle cell-related vaso-occlusive crisis within the previous 12 months while concurrently receiving hydroxyurea therapy.
  - Individual has experienced a sickle cell-related vaso-occlusive crisis within the previous 12 months and has an intolerance or contraindication to hydroxyurea therapy.
- Dose is 5 mg/kg IV at week 0, week 2 and every four weeks thereafter.

Eptinezumab-jjmr (Vyepti)

Effective for dates of service on or after Oct. 1, 2020, the IHCP covers J3032 – *Injection, eptinezumab-jjmr, 1 mg*. Prior authorization is required. The following medical necessity criteria must be met:

- All the following have either been tried and failed, or there is documented intolerance or contradiction for their use:
  - Propranolol or topiramate
  - Aimovig
  - Emgality
- Quantity does not exceed 3 mL/90 days

Eteplirsen (Exondys 51)

Eteplirsen (Exondys 51) is an antisense oligonucleotide indicated for the treatment of Duchenne muscular dystrophy (DMD).

The IHCP reimburses providers for HCPCS code J1428 – *Injection, eteplirsen, 10 mg*. Prior authorization is required for injections of eteplirsen. The following medical necessity criteria must be met:

- The member must have a diagnosis of DMD, with confirmed mutation of the DMD gene that is amenable to exon 51 skipping.
- The dosage is 30 mg/kg once weekly; patient weight must be provided to confirm dose.
- The prescriber must provide documentation of current clinical status (for example, Brooke Score, six-minute walk test and so on) to compare upon reevaluations of therapy.

Golodirsen (Vyondys 53)

The IHCP reimburses providers for HCPCS code J1429 – *Injection, golodirsen, 10 mg*. Prior authorization is required for injections of golodirsen. The following medical necessity criteria must be met:

- The member must have a diagnosis of DMD with confirmed mutation of the DMD gene that is amenable to exon 53 skipping.
- The dosage is 30mg/kg once weekly; patient weight must be provided to confirm dose.
- The prescriber has validated that member is not currently experiencing renal toxicity.

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 IHCP reimburses for HCPCS code J9226 – *Histrelin implant (Supprelin LA), 50 mg* only when it is billed with the ICD-10 diagnosis code E30.1 – *Precocious puberty*.

The workup for precocious puberty should include both physical and laboratory diagnostic confirmatory steps before treatment is initiated. 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 females 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 twice daily would not be tolerated or complied with.

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.

Histrelin Implant (Vantas)

Vantas is a subcutaneous drug-delivery system that contains the medicine histrelin. After it is placed under the skin, Vantas delivers histrelin continuously for 12 months. Vantas is a sterile, nonbiodegradable, diffusion-controlled Hydron polymer reservoir containing histrelin acetate, a synthetic nonapeptide analog of the naturally occurring gonadotropin-releasing hormone (GnRH), also known as luteinizing hormone-releasing hormone (LHRH), possessing a greater potency than the natural sequence hormone. Vantas is used to help relieve the symptoms of advanced prostate cancer; it is not a cure.

The IHCP reimburses providers for HCPCS code J9225 – *Histrelin implant (Vantas), 50 mg* only when billed with one of the following ICD-10 diagnosis codes:

- C61 – *Malignant neoplasm of prostate*
- Z85.46 – *Personal history of malignant neoplasm of prostate*
- R97.21 – *Rising PSA following treatment for 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 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 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.

Leuprolide Acetate (Fensolvi)

Effective for dates of service on or after July 1, 2021, the IHCP covers HCPCS code J1951 – *Injection, leuprolide acetate for depot suspension (Fensolvi), 0.25 mg*. Coverage of this code is restricted to diagnosis code E30.1 – *Precocious puberty*.

Claim details for J1951 reported without diagnosis code E30.1 will deny with EOB 6108 – *Histrelin implant limited to specific diagnosis*.

Nusinersen (Spinraza)

Nusinersen (Spinraza) is an intrathecal medication for the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients.

The IHCP reimburses providers for HCPCS code J2326 – *Injection, nusinersen, 0.1 mg.* Prior authorization is required for nusinersen. Nusinersen is considered medically necessary for the treatment of SMA in individuals who meet both criteria A and B:

- *Criteria A:* Documentation of confirmatory diagnosis by one of the following:
  - SMA diagnostic test results confirming zero copies of the SMN1 gene
  - Molecular genetic testing of 5q SMA for any of the following:
    - Homozygous gene deletion
    - Homozygous conversion mutation
    - Compound heterozygote
- *Criteria B:* Documentation of one of the following:
  - Genetic testing confirming no more than two copies of the SMN2 gene
  - SMA-associated symptoms before 6 months of age

> *Note: If the member has more than two copies of SMN2, but has point mutations on SMN2 exon 7, treatment would be considered medically necessary.*

Continuation of treatment with nusinersen beyond six months after the initiation of therapy, and every six months thereafter, is considered medically necessary for the treatment of SMA when individuals meet both of the following criteria:

- Initial therapy was determined to meet the preceding criteria (A and B).
- There is documentation of clinically significant improvement in SMA-associated symptoms (for example, progression, stabilization or decreased decline in motor function) compared to the predicted natural history trajectory of the disease.

Nusinersen is not considered medically necessary when used under the following treatment scenarios:

- Post onasemnogene abeparvovec-xioi treatment
- Concurrently with risdiplam

Onasemnogene Abeparvovec-xioi (Zolgensma)

The IHCP reimburses providers for Zolgensma (onasemnogene abeparvovec-xioi), a U.S. FDA-approved drug treatment for spinal muscular atrophy (SMA), with prior authorization.

Providers should bill for this physician-administered drug using HCPCS code J3399 – *Injection, onasemnogene abeparvovec-xioi, per treatment, up to* $5x10^{15}$ *vector genomes*.

Special authorization request procedures are required for this drug when it is provided under the medical benefit. Rather than submitting the PA request directly to Gainwell (either via the Portal or by mail using the standard PA form), providers must email PA requests for Zolgensma, including related documents and relevant contact information, to FSSA.IHCPReimbursement@fssa.IN.gov.

The IHCP established the following PA criteria to determine medical necessity for the coverage of Zolgensma:

- Have documentation of genetic testing confirming SMA resulting from bi-allelic mutations in the survival motor neuron 1 (SMN1) gene
- Have no more than two copies of SMN2 or displaying clinical symptoms of SMA

- Have documentation demonstrating negative presence of anti-AAV9 antibodies
- Have a gestational age of at least 37 weeks
- Be less than two years of age
- Have been prescribed Zolgensma treatment by, or in consultation with, a pediatric neurologist or child neurologist
- Have had no previous Zolgensma treatment
- Have a life expectancy of at least 12 months following treatment
- Have no evidence of advanced SMA, such as one or more of the following:
  - Complete paralysis of limbs
  - Permanent ventilator dependence, defined as:
    - Requires invasive ventilation (tracheostomy with positive pressure)
    - Respiratory assistance (including noninvasive ventilator support) for at least 16 hours per day, for at least 14 days (excluding acute, reversible illness or perioperative ventilation)

Note:	*The prescriber must provide documentation of current clinical status (for example, Brooke Score, six-minute walk test and so on) to compare upon reevaluations of therapy.*

Pegloticase (Krystexxa)

Pegloticase (Krystexxa) is an intravenous medication that breaks down uric acid. It is used for the treatment of chronic gout. IHCP reimbursement is available only when administered in a physician's office, consistent with IHCP policy concerning reimbursement for injectable pharmaceutical products.

The IHCP reimburses providers for HCPCS code J2507 – *Injection, pegloticase, 1 mg.* Prior authorization is required for pegloticase. Pegloticase may be considered medically necessary in patients with gout when criteria A, B and C are met:

- *Criteria A* – Symptomatic gout with one or more of the following:
  - Three gouty flares or more in previous 18 months
  - Presence of one or more tophi
  - Chronic gouty arthritis
- *Criteria B* – Serum uric acid level
  - Serum uric acid level greater than 8 mg/dL
- *Criteria C* – Treatment with oral xanthine oxidase inhibitors with one of the following:
  - A 90-day course of each of two xanthine oxidase inhibitors alternatives (such as allopurinol and febuxostat) is ineffective in normalizing serum uric acid levels to less than 6 mg/dL
  - Intolerance to two xanthine oxidase inhibitors alternatives (such as allopurinol and febuxostat)
  - Use of two xanthine oxidase inhibitors alternatives (such as allopurinol and febuxostat) is contraindicated

Pegloticase is considered investigational when used for all other conditions, including but not limited to hyperuricemia not associated with gout and asymptomatic hyperuricemia.

When prior authorization is approved, pegloticase may be authorized in quantities of one 8 mg infusion every two weeks, not to exceed 26 infusions in one year.

Romoszumab-aqqg (Evenity)

The IHCP reimburses providers for J3111 – *Injection, romosozumab-aqqg, 1 mg* (Evenity) when the following PA criteria are met:

- Postmenopausal woman with osteoporosis
- High risk for bone fracture
- History of failure, contraindication or intolerance to oral or intravenous bisphosphonate therapy
- No myocardial infraction or stroke in the previous year
- No uncorrected hypocalcemia

Coverage is limited to a one-year duration of therapy over the course of the member's lifetime.