From: dph.immunizations@ct.gov <noreply@everbridge.net>

Sent: Monday, October 2, 2023 2:17 PM

Subject: Nirsevimab Now Available through the CT Vaccine Program (CVP)



October 2, 2023

This communication is being sent to all key contacts at provider organizations enrolled in the CT Vaccine (Pediatric) Program (CVP) – please read this message in its entirety. Please feel free to share it with others in your organization who may benefit from the update. Note that all our communications are archived on our web site.

Dear CVP providers,

Nirsevimab (Beyfortis-Sanofi) is now available for order from the CVP for use in all infants and young children per the Advisory Committee on Immunization Practices (ACIP) recommendations available here. Nirsevimab is a monoclonal antibody product that is a passive immunization to prevent lower respiratory tract disease due to respiratory syncytial virus (RSV). While not technically a "vaccine" in a traditional sense (active immunization), it is being used in a manner similar to routine childhood vaccines and may be referred to as a vaccine by some entities.

The updated Vaccine Eligibility Criteria table is attached and will be posted on our web site. Also attached is a vaccine coding and billing sheet from Sanofi.

Below is a summary of the recommendations:

- ACIP recommends 1 dose of nirsevimab for all infants aged <8 months born during
 or entering their first RSV season (50 mg for infants weighing <5 kg [<11 lb] and 100
 mg for infants weighing ≥5 kg [≥11 lb]).
- ACIP recommends 1 dose of nirsevimab (200 mg, administered as two 100 mg injections given at the same time at different injection sites) for infants and children aged 8–19 months who are at increased risk for severe RSV disease and entering their second RSV season. The recommendations for nirsevimab apply to infants and children recommended to receive palivizumab by the American Academy of Pediatrics (AAP). These recommendations will be updated as new evidence becomes available.

Clinical Guidance

- In accordance with general best practices for immunization, simultaneous administration of nirsevimab with age-appropriate vaccines is recommended.
- Providers should administer nirsevimab shortly before the start of the RSV season (estimated to be October through end of March in Connecticut).

- Infants born shortly before or during the RSV season should receive nirsevimab within 1 week of birth.
- Nirsevimab administration can occur during the birth hospitalization or in the outpatient setting.
- Optimal timing for nirsevimab administration is shortly before the RSV season begins; however, nirsevimab may be administered to age-eligible infants and children who have not yet received a dose at any time during the season.
- Only a single dose of nirsevimab is recommended for an RSV season.
- AAP FAQs are available here.

Orders should be placed in CT WiZ as you do for your other CVP vaccines. For your initial orders, please request enough vaccine to last approximately one month. You may reorder as needed. Orders should be received within a week of when they are placed.

As always, thank you for your ongoing support and effort to support vaccination.

For the CT DPH Immunization Program, visit: Contact Us

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CODING AND BILLING SHEET

Immune Globulin Code

CPT®a code **90380 or 90381** should be assigned on all claims for Beyfortus. These codes describe a 0.5-mL dose and a 1-mL dose of this pediatric, once per season, passive immunization for RSVb. It is not necessary to use modifier-51 when reporting these codes with another procedure. See the grid below for more information on billing these codes.

CPT Code	Code Description	Suggested Use						
	Respiratory syncytial virus, monoclonal antibody, seasonal dose; 0.5 mL dosage, for intramuscular use	Bill 1 unit of 90380 when a 0.5-mL dose is provided.						
90381	Respiratory syncytial virus, monoclonal antibody,	Bill 1 unit of 90381 when a 1-mL dose is provided.						
	seasonal dose; 1 mL dosage, for intramuscular use	Bill 2 units of 90381 when a 2-mL dose is provided.						
Source: 2023 Current Procedural Terminology - all code descriptions are as defined by the American Medical Association.								

National Drug Codes (NDCs)

Some payers require an NDC in addition to the CPT code for the product. In such cases, it is important to format the NDC correctly or the claim will be denied and you will need to resubmit a corrected claim in order to be reconsidered for payment. Begin by determining if the payer requires the carton NDC or the unit-of-use NDC. On line 24A, place qualifier N4, the 11-digit NDC number (without hyphens), the Unit-of-Measure, and Units Dispensed. To convert the Beyfortus NDC to the required 11-digit format, add a leading zero in the middle section of numbers (ex. 49281-575-00 = 49281-**0**575-00). Unit-of-Measure, ML, is reported when the product is supplied in a liquid format. Units Dispensed is the actual decimal quantity administered. Continue to bill CPT code 90380 or 90381 and administration code 96372. Below is how to submit the NDCs for Beyfortus.

When the Payer Requires Carton NDC	When the Payer Requires Unit-of-Use NDC	Description
N449281057515 ML0.5	N449281057500 ML0.5	Carton of 5, 0.5-mL prefilled syringes (5x1)
N449281057415 ML1.0	N449281057488 ML1.0	Carton of 5, 1-mL prefilled syringes (5x1)
N449281057415 ML2.0	N449281057488 ML2.0	Carton of 5, 1-mL prefilled syringes (5x1)

Administration Code

The administration of an immune globulin is reported in addition to the immune globulin product code (ie, assign the code for the product along with the appropriate code for its administration). To appropriately code for administration of an immune globulin administered by intramuscular injection, use CPT code 96372. See the grid below for more information on billing this code.

Code	Code Description	Suggested Use						
	Therapeutic, prophylactic, or diagnostic injection	Bill 1 unit of 96372 when a 0.5-mL dose is administered.						
	(specify substance or drug); subcutaneous or	Bill 1 unit of 96372 when a 1-mL dose is administered.						
	intramuscular	Bill 2 units of 96372 when two 1-mL doses are administered.						
Source: 2023 Current Procedural Terminology - all code descriptions are as defined by the American Medical Association.								

Beyfortus is **indicated** for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease in:

- · Neonates and infants born during or entering their first RSV season.
- · Children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.

IMPORTANT SAFETY INFORMATION Contraindication

Beyfortus is contraindicated in infants and children with a history of serious hypersensitivity reactions, including anaphylaxis, to nirsevimab-alip or to any of the excipients.

Please see additional Important Safety Information continued on page 2.



Diagnosis Code (ICD-10-CM)^c

Below are the suggested diagnosis codes that may be appropriate when submitting claims for Beyfortus (nirsevimab-alip) and its administration. The ICD-10 code should be linked to both the Beyfortus code 90380 or 90381, and its administration code 96372. Assign the appropriate code based on review of the documentation in the medical record.

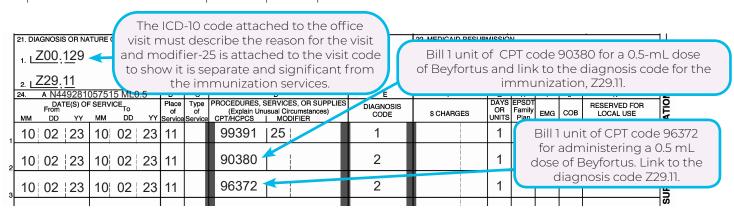
ICD-10-CM Code	Code Description	Suggested Use						
Z29. 11	Encounter for prophylactic immunotherapy for respiratory syncytial virus (RSV)	When a dose of RSV passive immunization is administered.						
Applicable High- Risk Condition	Applicable High-Risk Condition Code Description	When a dose of RSV passive immunization is administered due to a high risk condition, add Z29.11 and the applicable ICD-10 code that describes each patient's high-risk condition.						
Source: 2023 International Classification of Diseases, 10th Revision - Clinical Modification								

Billing for Visits and an Immunization

If an immunization is the only service provided, a visit is not billed. When a separate and significant visit is provided along with an immunization, bill for the visit and the immunization services. When an immunization is administered at any type of visit, the modifier -25 may need to be attached to the evaluation and management code along with an ICD-10 which describes the reason for the visit to identify that it is separate and significantly different than other services billed. Check with your payers to confirm their requirements regarding the use of the -25 modifier.

Billing Examples

An infant is seen for a well visit and receives a 0.5-mL dose of Beyfortus. The physician counsels the parent on the passive immunization. The patient's plan requires NDCs on claims.



Do you have questions on coverage or payment for Sanofi products? Contact a Sanofi Reimbursement Specialist (RS). Call 1-800-VACCINE (1-800-822-2463) and choose the prompt for the RS.

Visit <u>www.crackingthecodestraining.com</u> for on-demand coding and billing videos and resources for Sanofi products.

Visit the Coding Education and Reimbursement Support Page on <u>VaccineShop.com</u>® for additional coding resources for Sanofi products.

IMPORTANT SAFETY INFORMATION [CONTINUED] Warnings and Precautions

• **Hypersensitivity Including Anaphylaxis:** Serious hypersensitivity reactions, including anaphylaxis, have been observed with other human IgG1 monoclonal antibodies. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, initiate appropriate medications and/or supportive therapy.

Please see additional Important Safety Information continued on page 3.



Billing Examples continued

An infant is seen for a well visit and receives a 1-mL dose of Beyfortus. The nurse practitioner counsels the parent on the passive immunization. The patient's plan requires NDCs on claims.

1	The ICD-10 code attached to the office visit must describe the reason for the visit and modifier-25 is attached to the visit code. The ICD-10 code attached to the office bill 1 unit of CPT code 90381 for a 1-mL dose of Beyfortus and link to the diagnosis code for the immunization, Z29.11.													
24	A N44928105741 DATE(S) OF SERVI		.0	B Place	C	D PROCEDURES, SERVICES, OR SUPPLIES	100000	F	G DAYS	H EPSDT	1	J	K RESERVED FOR	N
N	From DD YY MM		YY	of	of	(Explain Unusual Circumstances) CPT/HCPCS MODIFIER	DIAGNOSIS CODE	\$ CHARGES	OR UNITS	Family Plan	MG	сов	LOCAL USE	ĬĖ
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2	05 23 10	05	23	11		90381	2		1	for	Bill 1 unit of CPT code 96372 for administering a 1-mL dose of Beyfortus. Link to the diagnosis code for the immunization Z29.11.			
	05 23 10) OF I	2	44		96372	2		1					
2						1	2		1	for Be				

A child less than 24 months old is seen for an evaluation and management visit and receives a 2-mL dose of Beyfortus. The registered nurse counsels the parent on the passive immunization. The patient's plan requires NDCs on claims.

The ICD-10 code attached to the office visit must describe the reason for the visit. Modifier -25 is attached to the visit to show it is separate and significant from the immunization services. The ICD-10 code attached to the office visit of CPT code 90381 for a 2-mL dose of Beyfortus and link to the diagnosis code for the immunization Z29.11 and the diagnosis code which describes the patient's high risk condition.									sis code for gnosis code			
24. A N449281057415 DATE(S) OF SERVICE From MM DD YY MM	To Place	of	D PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS I MODIFIER	DIAGNOSIS CODE	& CHARGES		EPSDT Family Plan	EMG	сов	RESERVED FOR LOCAL USE	ATIO	
	0 23 11	GGETVICE	99203 25	1		1			Bill	2 units of 96	⊣≦ 3772 for	
10 10 23 10 1	0 23 11		90381	1,2		2	Bill 2 units of 96372 for administering two 1-mL doses of					
10 10 23 10 1	0 23 11		96372	1,2		2	Beyfortus. Link to the diagnosis code Z29.11 and the diagnosis code					
							which describes the patient's high risk condition.					

Vaccines for Children (VFC) Billing

Be aware that many Medicaid plans stipulate which codes can be billed for administering immunizations available through the VFC program. Be sure to investigate the coding rules for your Medicaid plans, for this immune globulin immunization, in case the required coding is different than the coding explained here.

CVX and MVX Codes

CVX and MVX codes are used to populate immunization registries. The CVX code indicates which product was used and the MVX code indicates the manufacturer of the product. When a MVX (manufacturer) code is paired with a CVX (product administered) code, the specific trade named product can be identified. The CVX codes for Beyfortus are **306** for a 0.5-mL dose and **307** for a 1-mL dose. The MVX for Sanofi is **PMC**^d.

IMPORTANT SAFETY INFORMATION [CONTINUED] Warnings and Precautions

• Use in Individuals with Clinically Significant Bleeding Disorders: As with other IM injections, Beyfortus should be given with caution to infants and children with thrombocytopenia, any coagulation disorder or to individuals on anticoagulation therapy.

Most common adverse reactions with Beyfortus were rash (0.9%) and injection site reactions (0.3%).

Please see Prescribing Information for Beyfortus.

^a CPT (Current Procedural Terminology) is a registered trademark of the American Medical Association; ^b RSV = Respiratory syncytial virus; ^c ICD-10 = International Classification of Diseases, 10th Revision; ^d PMC = Pasteur Merieux Connaught.

The information contained in this Coding and Billing Sheet is provided for informational purposes only. Every reasonable effort has been made to verify the accuracy of the information; however, this quick reference is not intended to provide specific guidance on how to utilize, code, bill, or charge for any product or service. Health care providers should make the ultimate decision as to when to use a specific product based on clinical appropriateness for a particular patient. Third-party payment for medical products and services is affected by numerous factors and Sanofi Inc. cannot guarantee success in obtaining insurance payments.



Connecticut Vaccine Program (CVP) Eligibility Criteria as of October 2, 2023

Vaccine	Age Group		CPT			
		VFC	Code(s)			
		VFC	Non-VFC	Non-VFC	S-CHIP ²	
		Eligible ¹	Eligible	Eligible		
			Privately	Under-		
			Insured ²	Insured ²		
Hepatitis B	Newborns in hospital	YES	YES	YES	YES	90744
	Children 0–18 yrs	YES	YES	YES	YES	
Varicella	12 months–18 yrs	YES	YES	YES	YES	90716
Td	7–18 yrs ³	YES	YES	YES	YES	90714
MMR	12 months–18 yrs	YES	YES	YES	YES	90707
	College (any age)	YES	YES	YES	YES	
MMRV	12 months–12 yrs	YES	YES	YES	YES	90710
DTaP	2 months-6 yrs	YES	YES	YES	YES	90700
Hib	2–59 months	YES	YES	YES	YES	90647, 90648
IPV	2 months–18 yrs	YES	YES	YES	YES	90713
DTaP/IPV	4–6 yrs	YES	YES	YES	YES	90696
DTaP/IPV/Hep B	2–83 months	YES	YES	YES	YES	90723
DTaP/IPV/Hib	2–59 months	YES	YES	YES	YES	90698
DTaP/IPV/Hib/Hep B	2–59 months	YES	YES	YES	YES	90697
MCV high risk	2 months–10 yrs	YES	YES	YES	YES	90619, 90734
MCV routine	11–18 yrs	YES	YES	YES	YES	90619. 90734
Tdap	7–18 yrs	YES	YES	YES	YES	90715
PCV20	2 months–18 yrs	YES	YES	YES	YES	90677
PCV15	2 months-18 yrs	YES	YES	YES	YES	90671
PPSV23	2–18 yrs	YES	YES	YES	YES	90732
Influenza	6 months–18 yrs	YES	YES	YES	YES	90672, 90674,
						90686
Hepatitis A	12 months–18 yrs	YES	YES	YES	YES	90633
Rotavirus	6 weeks–8 months	YES	YES	YES	YES	90680, 90681
HPV	9, 10, 15, and 16 yrs	YES	NO	YES	YES	90651
	11–14 & 17–18 yrs	YES	YES	YES	YES	
MenB high risk	10–18 yrs	YES	YES	YES	YES	90620, 90621
MenB routine	16–18 yrs	YES	YES	YES	YES	90620, 90621
RSV	Infants < 8 months	YES	YES	YES	YES	90380, 90381
RSV high risk	8–19 months	YES	YES	YES	YES	90380, 90381
COVID-19	6 months–18 yrs	YES	YES	YES	YES	91304, 91318,
	-					91319, 91320,
		<u> </u>		L	<u> </u>	91321, 91322

^{1.} VFC eligibility is as follows: (a) Medicaid enrolled; (b) uninsured; (c) American Indian/Alaskan native; or (d) underinsured seen at an FQHC.

As of July 1, 2023, the only childhood vaccine not universally available from the CVP is HPV for privately insured patients 9 & 10, & 15 & 16 years of age. Providers can purchase this vaccine privately and submit billing requests to the appropriate insurer in accordance with normal billing procedures.



^{2.} Non-VFC children refers to patients who have private insurance that covers the cost of immunizations, patients that are under-insured for some or all vaccines seen by a private provider; and S-CHIP children (those children enrolled in HUSKY B).

^{3.} Td vaccine can be given to children 7-18 years of age to complete their primary series, or to those children 7-18 years of age who need a tetanus containing vaccine and cannot receive Tdap.