ZYNYZ®
retifanlimab-dlwr
Injection 500 mg

BILLING AND CODING GUIDE

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- Facilitating Coverage and Coding
- Coverage, Coding, and Payment in the Physician Office Setting
- Coverage, Coding, and Payment in the Hospital Outpatient Setting
- Provider Readiness - Process and Tips
- IncyteCARES - Program Overview

Please note this information is provided for your background education and is not intended to serve as guidance for specific coding, billing, and claims submissions. Decisions on which codes best describe the services provided must be made by individual providers based on specific payer guidance and requirements.

Incyte cannot guarantee payment of any claim and providers should contact third-party payers for specific information on their coding, coverage, and payment policies as needed.

For questions regarding ZYNYZ reimbursement and access, please call IncyteCARES at 1-855-452-5234 Monday through Friday, 8 AM – 8 PM ET.

Introduction

This Billing and Coding Guide is intended to provide an overview of ZYNYZ® (retifanlimab-dlwr) coding and coverage information. Please use this guide to support the reimbursement process and as a source of information on services available through IncyteCARES for ZYNYZ.

While this guide provides information on navigating the reimbursement process, please note all enclosed coding information is for reference purposes only. Incyte cannot guarantee payment of any claim and providers should contact third-party payers for specific information on their coding, coverage, and payment policies as needed.

ZYNYZ is indicated for the treatment of adult patients with metastatic or recurrent locally advanced Merkel cell carcinoma (MCC).

This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

IMPORTANT SAFETY INFORMATION

Severe and Fatal Immune-Mediated Adverse Reactions

Important immune-mediated adverse reactions listed may not be inclusive of all possible severe and fatal immune-mediated reactions.

Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue, can occur at any time after starting or discontinuing treatment with a PD-1/PD-L1–blocking antibody, and can affect more than one body system simultaneously.

Monitor patients closely for symptoms and signs that may be clinical manifestations of such reactions. Early identification and management of immune-mediated adverse reactions are essential to ensure safe use of PD-1/PD-L1–blocking antibodies. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. If suspected, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate.

Withhold or permanently discontinue ZYNYZ depending on severity. In general, if ZYNYZ requires interruption or discontinuation, administer systemic corticosteroid therapy (1-2 mg/kg/day prednisone or equivalent) until improvement to ≤ Grade 1. Then, initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose adverse reactions are not controlled with corticosteroids.

Immune-Mediated Pneumonitis

ZYNYZ can cause immune-mediated pneumonitis. Immune-mediated pneumonitis occurred in 3% (13/440) of patients, including fatal (0.2%), Grade 3 (0.9%), and Grade 2 (1.4%) reactions. Pneumonitis led to permanent discontinuation of ZYNYZ in 1 patient and withholding in 0.9%.

Systemic corticosteroids were required in 77% (10/13) of patients. Pneumonitis resolved in 10 of the 13 patients.

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Facilitating Coverage and Coding

EFFECTIVE OCTOBER 1, 2023, ZYNYZ HAS A UNIQUE J-CODE

J9345:
Injection, retifanlimab-dlwr, 1 mg

The permanent J-code for ZYNYZ is effective for claims on or after October 1, 2023.

Understanding a payer's specific process and instructions is important when submitting a claim for reimbursement as payer requirements regarding detailed claim form information may vary. Please refer to the tips below and always consult a payer's individual policies to ensure you are following their specific requirements.

What can I do to support timely reimbursement of ZYNYZ claims?

- **Verify accuracy** of patient information
- **Use the ZYNYZ specific J-code:** J9345 (Injection, retifanlimab-dlwr, 1 mg) when completing the 1450 or 1500 Claims Form
- **Refer to the ZYNYZ Billing and Coding Guide** for appropriate codes (e.g., HCPCS, CPT, ICD-10-CM)
  - Special billing instructions may be required in Box 19 of the CMS-1500 Claim Form (Additional Claim Information) to ensure the payer has enough information to adjudicate the claim correctly
- **Include correct number** of units administered
- **Include the correct modifier** - JZ Modifier must be reported for dates of service on or after July 1, 2023 when no product is discarded
- **Ensure accuracy** of the following information needed to process the claim:
  - Correct NDC Format (use 10- or 11-digit format based on payer requirements)
  - Prior Authorization Number (if applicable)
- **Follow the payer's recommendations** for providing additional information (e.g., medical records)
- **Make sure** electronic claims are successfully submitted
- **Stay up to date** with payer coverage policies

The information herein is provided for educational purposes only. Insurance coverage and reimbursement are not guaranteed. Coverage and reimbursement may vary significantly by payer, plan, patient, and setting of care. It is the sole responsibility of the health care provider to select the proper codes and ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.

For Billing and Coding or Reimbursement Questions, or to Request Support From a Field Access Manager,
Call 1-855-452-5234, M - F 8 AM to 8 PM ET

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Coverage, Coding, and Payment in the Physician Office Setting

For Medicare patients, ZYNYZ® (retifanlimab-dlwr) will be covered under Medicare Part B when used for an FDA-approved indication and when medically reasonable and necessary. There are no prior authorization requirements for ZYNYZ under traditional fee-for-service Medicare plans.

For patients enrolled in Medicaid, a Medicare Advantage plan, or a commercial health plan, coverage of ZYNYZ will vary by payer. Some payers may also apply utilization restrictions for ZYNYZ.

Incyte cannot guarantee payment of any claim and providers should contact third-party payers for specific information on their coding, coverage, and payment policies as needed.

Please refer to the table below to support appropriate claims processing for ZYNYZ.

MCC ICD-10-CM DIAGNOSIS CODES

C4A0	Merkel cell carcinoma of lip	**C4A4**	Merkel cell carcinoma of scalp and neck
C4A10	Merkel cell carcinoma of unspecified eyelid, including canthus	**C4A51**	Merkel cell carcinoma of anal skin
C4A111	Merkel cell carcinoma of right upper eyelid, including canthus	**C4A52**	Merkel cell carcinoma of skin of breast
C4A112	Merkel cell carcinoma of right lower eyelid, including canthus	**C4A59**	Merkel cell carcinoma of other part of trunk
C4A121	Merkel cell carcinoma of left upper eyelid, including canthus	**C4A60**	Merkel cell carcinoma of unspecified upper limb, including shoulder
C4A122	Merkel cell carcinoma of left lower eyelid, including canthus	**C4A61**	Merkel cell carcinoma of right upper limb, including shoulder
C4A20	Merkel cell carcinoma of unspecified ear and external auricular canal	**C4A62**	Merkel cell carcinoma of left upper limb, including shoulder
C4A21	Merkel cell carcinoma of right ear and external auricular canal	**C4A70**	Merkel cell carcinoma of unspecified lower limb, including hip
C4A22	Merkel cell carcinoma of left ear and external auricular canal	**C4A71**	Merkel cell carcinoma of right lower limb, including hip
C4A30	Merkel cell carcinoma of unspecified part of face	**C4A72**	Merkel cell carcinoma of left lower limb, including hip
C4A31	Merkel cell carcinoma of nose	**C4A8**	Merkel cell carcinoma of overlapping sites
C4A39	Merkel cell carcinoma of other parts of face	**C4A9**	Merkel cell carcinoma, unspecified

ZYNYZ DRUG AND ADMINISTRATION CODES

National Drug Code (NDC)	Drug Administration / CPT Codes	Modifier	HCPCS Code
10-digit: 50881-006-03 11-digit: 50881-**0**006-03	**96413** (Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial drug)	**JZ** (Modifier for recording zero product wastage)	**J9345** (Injection, retifanlimab-dlwr, 1 mg)

PAYMENT METHODOLOGY

Medicare	Commercial Payers and Medicaid
Average Sales Price (ASP) +6%[a]	Most non-Medicare payers will pay separately for ZYNYZ; however payment rates will vary by payer and provider contract

[a] If Medicare sequestration is in effect, a statutory reduction to the payment is applied. Please visit CMS.gov for more information.

ZYNYZ® retifanlimab-dlwr Injection 500 mg

Coding and Billing Reference Guide
Example CMS-1500 Claim Form – Physician Office Setting

This example form is provided for guidance and reference only.

ZYNYZ® (retifanlimab-dlwr) and the associated services provided in the physician's office are billed on the CMS-1500 Claim Form or its electronic equivalent. An example CMS-1500 Claim Form is provided below. It is always the provider's responsibility to determine the appropriate healthcare setting, and to submit true and correct claims for the products and services rendered. **Incyte cannot guarantee payment of any claim and providers should contact third-party payers for specific information on their coding, coverage, and payment policies as needed.**

Box 19
Payers require drug name, route of administration, NDC, and total dosage

Check with your payer to verify specific requirements, including use of the 10-digit or 11-digit NDC

Box 21
Enter appropriate diagnosis code(s)

Box 24 A–B
Enter the date of service and the appropriate place of service code

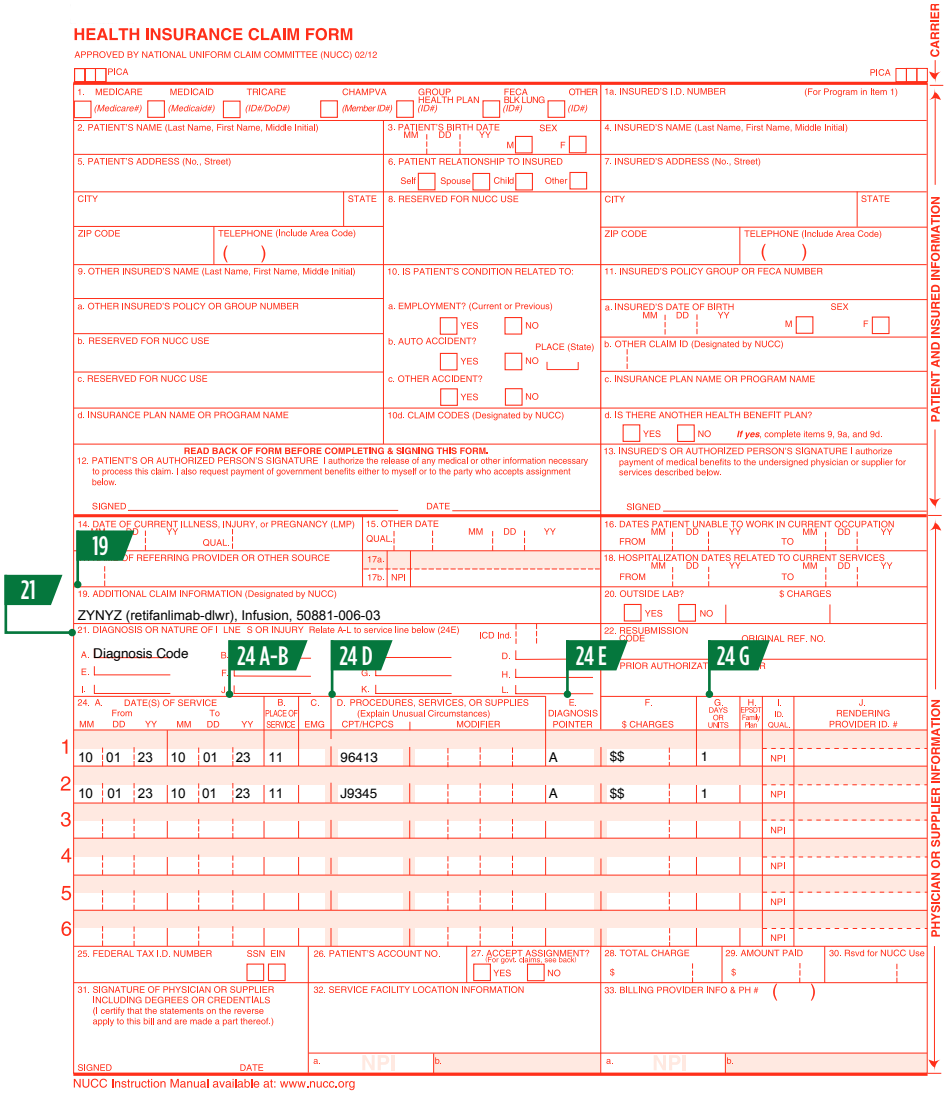
Box 24 D
Enter the appropriate drug and administration codes, for example:

- Drug - J9345 (Injection, retifanlimab-dlwr, 1 mg), effective 10/01/2023
- Administration - 96413 (chemo infusion for 1st hour, single or initial drug)

Note: Include the JZ modifier if no amount of drug was discarded

Box 24 E
Specify the diagnosis, from Box 21, that relates to the drug or procedure listed in Box 24 D

Box 24 G
Enter the number of service units for each line item



IMPORTANT SAFETY INFORMATION (CONT'D)

Immune-Mediated Colitis

ZYNYZ can cause immune-mediated colitis. Cytomegalovirus infections/reactivations have occurred in patients with corticosteroid-refractory immune-mediated colitis treated with PD-1/PD-L1–blocking antibodies. In cases of corticosteroid-refractory colitis, consider repeating infectious workup to exclude alternative etiologies.

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Coverage, Coding, and Payment in the Hospital Outpatient Setting

For Medicare patients, ZYNYZ® (retifanlimab-dlwr) will be covered under Medicare Part B when used for an FDA-approved indication and when medically reasonable and necessary. There are no prior authorization requirements for ZYNYZ under traditional fee-for-service Medicare plans.

For patients enrolled in Medicaid, a Medicare Advantage plan, or a commercial health plan, coverage of ZYNYZ will vary by payer. Some payers may also apply utilization restrictions for ZYNYZ.

Incyte cannot guarantee payment of any claim and providers should contact third-party payers for specific information on their coding, coverage, and payment policies as needed.

Please refer to the table below to support appropriate claims processing for ZYNYZ.

MCC ICD-10-CM DIAGNOSIS CODES

C4A0	Merkel cell carcinoma of lip	**C4A4**	Merkel cell carcinoma of scalp and neck
C4A10	Merkel cell carcinoma of unspecified eyelid, including canthus	**C4A51**	Merkel cell carcinoma of anal skin
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ZYNYZ DRUG AND ADMINISTRATION CODES

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PAYMENT METHODOLOGY

Medicare	Commercial Payers and Medicaid
Average Sales Price (ASP) +6%[a]	Most non-Medicare payers will pay separately for ZYNYZ; however payment rates will vary by payer and provider contract

[a] If Medicare sequestration is in effect, a statutory reduction to the payment is applied. Please visit CMS.gov for more information.
OPPS, Outpatient Prospective Payment System.

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Coding and Billing Reference Guide
Example CMS-1450 Claim Form – Hospital Outpatient Setting

This example form is provided for guidance and reference only.

ZYNYZ® (retifanlimab-dlwr) and the associated services provided in a hospital outpatient setting are billed on the CMS-1450 Claim Form or its electronic equivalent. An example CMS-1450 Claim Form is provided below. It is always the provider's responsibility to determine the appropriate healthcare setting, and to submit true and correct claims for the products and services rendered. **Incyte cannot guarantee payment of any claim and providers should contact third-party payers for specific information on their coding, coverage, and payment policies as needed.**

Box 42
List the appropriate revenue code for each service provided. Drugs that are billed with HCPCS codes usually require revenue code 0636 (drugs requiring detailed coding)

Box 43
For each item, enter the description of the revenue code used

Box 44
Enter the appropriate HCPCS codes, for example:

- Drug - J9345 (Injection, retifanlimab-dlwr, 1 mg), effective 10/01/2023
- Administration - 96413 (chemo infusion for 1st hour, single or initial drug)

Note: Include the JZ modifier if no amount of drug was discarded

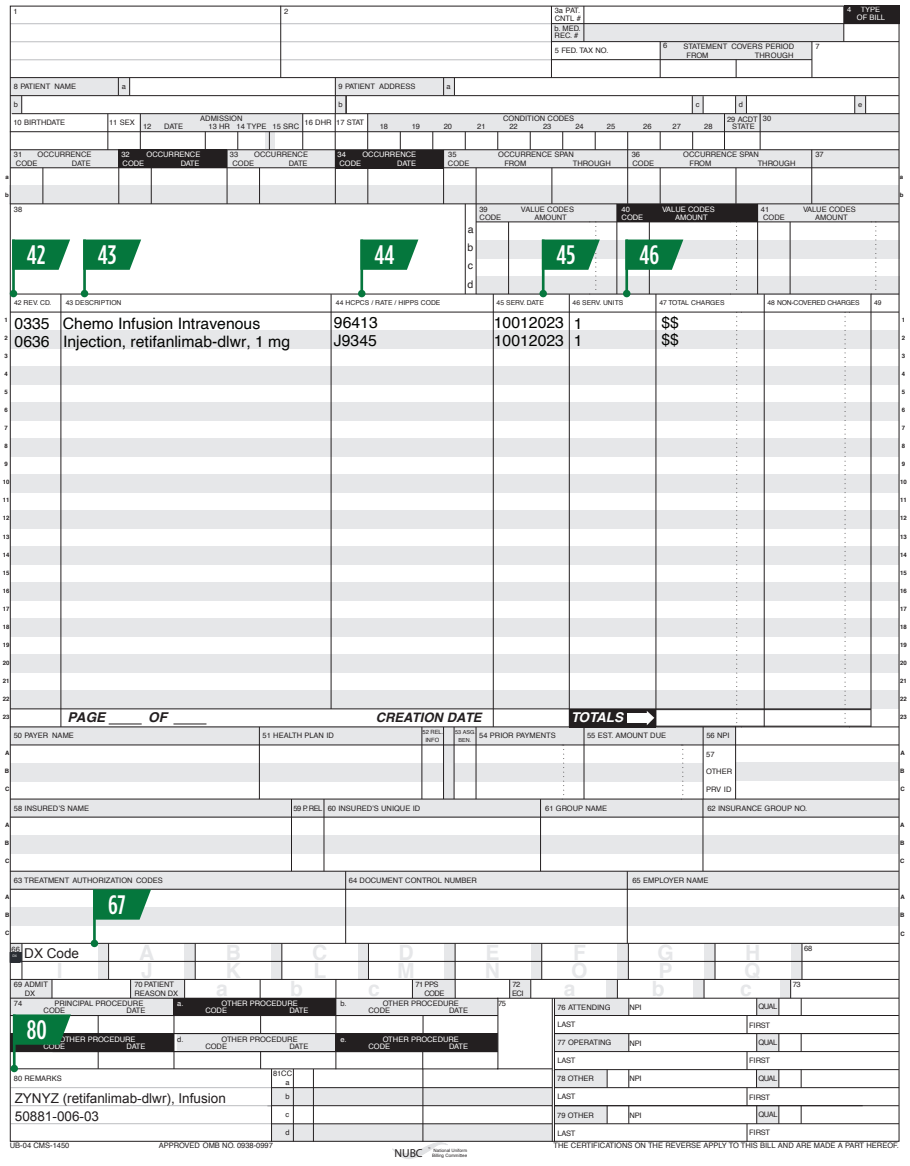
Box 45
Enter the service date

Box 46
Enter the number of service units for each line item

Box 67
Enter the primary diagnosis code

Box 80
Payers require drug name, route of administration, NDC, and total dosage

Check with your payer to verify specific requirements, including use of the 10-digit or 11-digit NDC



IMPORTANT SAFETY INFORMATION (CONT'D)

Immune-mediated colitis occurred in 1.6% (7/440) of patients, including Grade 4 (0.2%), Grade 3 (0.2%), and Grade 2 (0.7%). Colitis led to permanent discontinuation of ZYNYZ in 1 patient and withholding in 0.9%.

Systemic corticosteroids were required in 71% (5/7) of patients. Colitis resolved in 4/7 patients.

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Provider Readiness—Process and Tips

When preparing to treat a patient with ZYNYZ® (retifanlimab-dlwr) as prescribed, consider the steps below to facilitate patient access, proper claims submission, and appropriate reimbursement. For questions or support on any of these steps, please reach out to IncyteCARES at **1-855-452-5234** or visit **HCP.IncyteCARES.com/ZYNYZ** to complete an Enrollment Form.

1 — **Research and understand** patient-specific benefits and coverage for ZYNYZ

2 — If there are access concerns, be sure to **enroll your patient** in IncyteCARES to understand potential financial assistance options that may be available for eligible patients

3 — **Schedule the patient** for his or her first ZYNYZ infusion

4 — **Purchase ZYNYZ** (if not already in inventory) through one of the following Specialty Distributors:

SPECIALTY DISTRIBUTORS		
CardinalHealth	cencora	McKESSON

Prescribers who do not wish to use buy-and-bill should check with their preferred Specialty Pharmacy for availability. Specialty Pharmacies may obtain access to ZYNYZ through the Specialty Distributors listed above

5 — After treatment, **complete and submit a claim** to the payer, including all necessary information. If no product was discarded, include the JZ modifier to attest to no wastage

IMPORTANT SAFETY INFORMATION (CONT'D)

Immune-Mediated Hepatitis

ZYNYZ can cause immune-mediated hepatitis. Immune-mediated hepatitis occurred in 3% (13/440) of patients, including Grade 4 (0.2%), Grade 3 (2.3%), and Grade 2 (0.5%). Hepatitis led to permanent discontinuation of ZYNYZ in 1.4% of patients and withholding in 0.9%.

Systemic corticosteroids were required in 85% (11/13) of patients. Hepatitis resolved in 6/13 patients.

Immune-Mediated Endocrinopathies

Adrenal Insufficiency

ZYNYZ can cause primary or secondary adrenal insufficiency. For ≥ Grade 2 adrenal insufficiency, initiate symptomatic treatment per institutional guidelines, including hormone replacement as clinically indicated. Withhold or permanently discontinue ZYNYZ depending on severity.

IncyteCARES

Contact IncyteCARES at
1-855-452-5234 or
HCP.IncyteCARES.com/ZYNYZ

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IncyteCARES – Program Overview

We're Here to Support Your Eligible Patients During Treatment

Our mission is to help your patients start and stay on therapy by assisting with access and as-needed support.

When You Enroll a Patient, an IncyteCARES Representative Will:

- Call your patient to welcome them and explain their insurance coverage for ZYNYZ® (retifanlimab-dlwr)
- Assess patient's eligibility for savings or financial assistance programs,* and help them enroll
- Explain the additional support and resources available to them during treatment

* Terms and conditions apply. Program terms may change at any time.

For Eligible Patients With Commercial Health Insurance

IncyteCARES for ZYNYZ Savings Program

Eligible patients can receive ZYNYZ for as little as $15, subject to certain limits†

To qualify, patients must:

- Have commercial healthcare coverage. Patients insured under federal or state government healthcare programs—including Medicare Part B, Medicare Advantage, Medicaid, TRICARE or any state medical or pharmaceutical assistance program—are not eligible. Patients without healthcare coverage are also not eligible
- Be a resident of the United States or Puerto Rico
- Have a valid prescription for ZYNYZ for an FDA-approved use

† Uninsured, cash-paying, or Alternate Funding Program (AFP) patients are not eligible. Not valid for patients insured through Medicare Part B, Medicare Advantage, Medicaid, TRICARE, or any state medical or pharmaceutical assistance program. Patient enrollment in a copay adjustment program, such as a maximizer or accumulator program, may impact the value of this offer. Annual benefit maximum applies, as may other restrictions. Program benefit applies to medication cost only and does not cover any costs to administer the medication. Valid prescription for ZYNYZ® (retifanlimab-dlwr) for an FDA-approved indication or compendia-recognized use is required. Please see the full Patient Terms and Conditions or call IncyteCARES for ZYNYZ at **1-855-452-5234**. Update effective as of January 1, 2024.

IMPORTANT SAFETY INFORMATION (CONT'D)

Adrenal insufficiency occurred in 0.7% (3/440) of patients, including Grade 3 (0.5%) and Grade 2 (0.2%). ZYNYZ was permanently discontinued in no patients and was withheld for 1 patient with adrenal insufficiency.

All patients required systemic corticosteroids. Adrenal insufficiency resolved in 1 of the 3 patients.

Hypophysitis

ZYNYZ can cause immune-mediated hypophysitis. Hypophysitis can present with acute symptoms associated with mass effect such as headache, photophobia, or visual field cuts, and can cause hypopituitarism. Initiate hormone replacement as clinically indicated. Withhold or permanently discontinue ZYNYZ depending on severity.

Hypophysitis occurred in 0.5% (2/440, both Grade 2) of patients. No patients discontinued or withheld ZYNYZ due to hypophysitis.

All patients required systemic steroids. Hypophysitis resolved in 1 of the 2 patients.

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IncyteCARES – Program Overview

Enroll Your Eligible Patients in IncyteCARES for ZYNYZ® (retifanlimab-dlwr)

Completing the enrollment form takes about 15 minutes. Simply download, complete, and fax it. Visit **HCP.IncyteCARES.com/ZYNYZ** for more information.

Other Financial Assistance and Support Options

When you enroll your patient in IncyteCARES for ZYNYZ, we will also review their eligibility for the following programs.

For Eligible Patients Who Are Uninsured or Underinsured for ZYNYZ
IncyteCARES for ZYNYZ Patient Assistance Program

For All Patients
Information About Nonprofit or Other Support Organizations

Questions?
Call IncyteCARES for ZYNYZ at **1-855-452-5234**, Monday through Friday, 8 AM - 8 PM ET

Please see **HCP.IncyteCARES.com/ZYNYZ** for full program terms and conditions.

IMPORTANT SAFETY INFORMATION (CONT'D)

Thyroid Disorders

ZYNYZ can cause immune-mediated thyroid disorders. Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism. Initiate hormone replacement or medical management of hyperthyroidism as clinically indicated. Withhold or permanently discontinue ZYNYZ depending on severity.

Thyroiditis occurred in 0.7% (3/440, all Grade 1) of patients. No patients discontinued or withheld ZYNYZ due to thyroiditis. Thyroiditis resolved in 1 of the 3 patients.

Hypothyroidism

Hypothyroidism occurred in 10% (42/440) of patients receiving ZYNYZ, including Grade 2 (4.8%). No patients discontinued due to hypothyroidism. ZYNYZ was withheld in 0.5% of patients.

Systemic corticosteroids were required for 1 patient, and 79% (33/42) of patients received endocrine therapy.

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IMPORTANT SAFETY INFORMATION (CONT'D)

Hyperthyroidism

Hyperthyroidism occurred in 6% (24/440) of patients receiving ZYNYZ® (retifanlimab-dlwr), including Grade 2 (2.5%). ZYNYZ was not discontinued in any patient and was withheld in 1 patient. Systemic corticosteroids were required for 13% (3/24) of patients, and 46% (11/24) of patients received endocrine therapy.

Type 1 Diabetes Mellitus, Which Can Present with Diabetic Ketoacidosis

Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Initiate treatment with insulin as clinically indicated. Withhold ZYNYZ depending on severity.

Type 1 diabetes mellitus occurred in 0.2% (1/440) of patients, including Grade 3 (0.2%) adverse reactions.

Immune-Mediated Nephritis with Renal Dysfunction

ZYNYZ can cause immune-mediated nephritis. Immune-mediated nephritis occurred in 1.6% (7/440) of patients receiving ZYNYZ, including Grade 4 (0.5%), Grade 3 (0.7%), and Grade 2 (0.5%). Nephritis led to permanent discontinuation of ZYNYZ in 0.9% of patients and withholding in 1 patient.

Systemic corticosteroids were required in 57% (4/7) of patients. Nephritis resolved in 3/7 patients.

Immune-Mediated Dermatologic Adverse Reactions

ZYNYZ can cause immune-mediated rash or dermatitis. Bullous and exfoliative dermatitis, including Stevens-Johnson syndrome, drug rash with eosinophilia and systemic symptoms, and toxic epidermal necrolysis, has occurred with PD-1/PD-L1–blocking antibodies. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate non-exfoliative rashes. Withhold or permanently discontinue ZYNYZ depending on severity.

Immune-mediated skin reactions occurred in 8% (36/440) of patients, including Grade 3 (1.1%) and Grade 2 (7%). Immune-mediated dermatologic adverse reactions led to permanent discontinuation of ZYNYZ in 1 patient and withholding in 2.3% of patients.

Systemic corticosteroids were required in 25% (9/36) of patients. Immune-mediated dermatologic adverse reactions resolved in 75% (27/36) of patients.

Other Immune-Mediated Adverse Reactions

The following clinically significant immune-mediated adverse reactions occurred at an incidence of < 1% in 440 patients who received ZYNYZ or were reported with the use of other PD-1/PD-L1–blocking antibodies, including severe or fatal cases.

Cardiac/vascular: myocarditis, pericarditis, vasculitis

Gastrointestinal: pancreatitis, to include increases in serum amylase and lipase levels, gastritis, duodenitis

Musculoskeletal: myositis/polymyositis, rhabdomyolysis (and associated sequelae, including renal failure), arthritis, polymyalgia rheumatica

Neurological: meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis (including exacerbation), Guillain-Barré syndrome, nerve paresis, autoimmune neuropathy

Ocular: uveitis, iritis, and other ocular inflammatory toxicities. Some cases can be associated with retinal detachment. Various grades of visual impairment to include blindness can occur. If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada–like syndrome, as this may require treatment with systemic steroids to reduce the risk of permanent vision loss.

Endocrine: hypoparathyroidism

Other (Hematologic/Immune): hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenic purpura, solid organ transplant rejection, other transplant (including corneal graft) rejection.

Infusion-Related Reactions

A severe infusion-related reaction (Grade 3) occurred in 1 (0.2%) of 440 patients. Monitor patients for signs and symptoms; interrupt or slow the rate of infusion or permanently discontinue ZYNYZ based on severity of reaction. Consider premedication with an antipyretic and/or an antihistamine for patients who have had previous systemic reactions to infusions of therapeutic proteins.

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IMPORTANT SAFETY INFORMATION (CONT'D)

Complications of Allogeneic HSCT

Fatal and other serious complications can occur in patients who receive allogeneic hematopoietic stem cell transplantation (HSCT) before or after being treated with a PD-1/PD-L1–blocking antibody. Transplant-related complications include hyperacute graft-versus-host disease (GVHD), acute GVHD, chronic GVHD, hepatic veno-occlusive disease after reduced intensity conditioning, and steroid-requiring febrile syndrome (without an identified infectious cause), which may occur despite intervening therapy between PD-1/PD-L1 blockade and allogeneic HSCT.

Follow patients closely for evidence of transplant-related complications and intervene promptly. Consider the benefit versus risks of treatment with a PD-1/PD-L1–blocking antibody prior to or after an allogeneic HSCT.

Embryo-Fetal Toxicity

ZYNYZ® (retifanlimab-dlwr) can cause fetal harm when administered to a pregnant woman. Animal studies have demonstrated that inhibition of the PD-1/PD-L1 pathway can lead to increased risk of immune-mediated rejection of the developing fetus, resulting in fetal death. Advise women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment and for 4 months after the last dose.

Lactation

Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment and for 4 months after the last dose.

Adverse Reactions

The safety of ZYNYZ was evaluated in 105 patients with metastatic or recurrent locally advanced MCC.

Serious adverse reactions occurred in 22% of patients receiving ZYNYZ. The most frequent serious adverse reactions (≥ 2% of patients) were fatigue, arrhythmia, and pneumonitis.

Permanent discontinuation of ZYNYZ due to an adverse reaction occurred in 11% of patients. These included asthenia, atrial fibrillation, concomitant disease progression of chronic lymphocytic leukemia, demyelinating polyneuropathy, eosinophilic fasciitis, increased transaminases, infusion-related reaction, lung disorder, pancreatitis, polyarthritis, and radiculopathy (1 patient each).

Dosage interruptions due to an adverse reaction occurred in 25% of patients. Adverse reactions or laboratory abnormalities that required dosage interruption in ≥ 2% of patients were increased transaminases, increased lipase, increased amylase, pneumonitis, and pyrexia.

The most common (≥ 10%) adverse reactions were fatigue, musculoskeletal pain, pruritus, diarrhea, rash, pyrexia, and nausea.

You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Incyte Corporation at 1-855-463-3463.

Please see the full Prescribing Information for ZYNYZ for additional Important Safety Information.

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