AXYCIS™
(cisplatin) Injection

BILLING & CODING GUIDE

AVYXA

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The contents herein provide general coverage, coding, and payment information about AXYCIS. The information within this guide was obtained from third-party sources and is made available for reference only. It is not exhaustive, is subject to change, and does not constitute billing, coding, or legal advice. Healthcare professionals are responsible for determining which code(s), charge(s), if any, appropriately reflect a service or diagnosis. It is the healthcare professional's responsibility to determine medical necessity and provide adequate documentation. AVYXA Pharma, LLC does not guarantee coverage or payment. Payment and coverage vary by payer. Questions about coding, coverage, and payment may be directed to the applicable third-party payer, reimbursement specialist, and/or legal counsel.

CMS: Centers for Medicare & Medicaid Services; CPT: Current Procedural Terminology; HCPCS: Healthcare Common Procedure Coding System; ICD: International Classification of Diseases; NDC: National Drug Code

Please see Important Safety Information, including **Boxed Warning** on pages 3 and 13 and full Prescribing Information for AXYCIS.

INDICATIONS AND IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING

INDICATIONS

Advanced Testicular Cancer

AXYCIS™ is indicated for the treatment of advanced testicular cancer.

Advanced Ovarian Cancer

AXYCIS is indicated for the treatment of advanced ovarian cancer.

Advanced Bladder Cancer

AXYCIS is indicated for the treatment of advanced bladder cancer.

IMPORTANT SAFETY INFORMATION

WARNING: NEPHROTOXICITY, PERIPHERAL NEUROPATHY, NAUSEA AND VOMITING, AND MYELOSUPPRESSION.

- **Nephrotoxicity: AXYCIS can cause severe renal toxicity, including acute renal failure. Severe renal toxicities are dose-related and cumulative. Ensure adequate hydration and monitor renal function and electrolytes. Consider dose reductions or alternative treatments in patients with renal impairment.**
- **Peripheral Neuropathy: AXYCIS can cause dose-related peripheral neuropathy that becomes more severe with repeated courses of the drug.**
- **Nausea and Vomiting: AXYCIS can cause severe nausea and vomiting. Administer pre-treatment and post-treatment antiemetics as clinically indicated.**
- **Myelosuppression: AXYCIS can cause severe myelosuppression with fatalities due to infections. Monitor blood counts accordingly. Interruption of therapy may be required.**

CONTRAINDICATIONS

AXYCIS is contraindicated in patients with severe hypersensitivity to cisplatin.

WARNINGS AND PRECAUTIONS

Nephrotoxicity

AXYCIS can cause dose-related nephrotoxicity, including acute renal failure that becomes more prolonged and severe with repeated courses of the drug. Renal toxicity typically begins during the second week after a dose of AXYCIS. Patients with renal impairment, geriatric patients, patients who are taking other nephrotoxic drugs, or patients who are not well hydrated may be more susceptible to nephrotoxicity.

Ensure adequate hydration before, during, and after AXYCIS administration. Measure serum creatinine, blood urea nitrogen, creatinine clearance, and serum electrolytes including magnesium prior to initiating therapy, and as clinically indicated. Consider magnesium supplementation as clinically needed.

Consider alternative treatments or reduce the dose of AXYCIS for patients with renal impairment or who develop significant reductions in creatinine clearance during treatment with AXYCIS according to clinical treatment guidelines.

Peripheral Neuropathy

AXYCIS can cause dose-related peripheral neuropathy that becomes more severe with repeated courses of the drug. Neurologic symptoms can occur after a single dose. Neuropathy can also have a delayed onset from 3 to 8 weeks after the last dose of AXYCIS. Manifestations include paresthesias in a stocking-glove distribution, areflexia, and loss of proprioception and vibratory sensation. The neuropathy may progress further even after stopping treatment. Peripheral neuropathy may be irreversible in some patients.

Prolonged treatment, treatment with other platinum-containing therapies, or use in combination with other drugs that cause peripheral neuropathy may increase the incidence or severity of peripheral neuropathy. Geriatric patients may be more susceptible to peripheral neuropathy.

Monitor for signs and symptoms of peripheral neuropathy. Withhold, reduce, or discontinue AXYCIS depending on the severity and persistence of peripheral neuropathy as clinically indicated.

Nausea and Vomiting

AXYCIS is a highly emetogenic antineoplastic agent. Administer pre-treatment and post-treatment antiemetics as clinically indicated. Without antiemetic therapy, marked nausea and vomiting occur in almost all patients treated with cisplatin and may be so severe that the drug must be discontinued. Nausea and vomiting may begin within 1 to 4 hours after treatment and last up to 72 hours. Maximal intensity occurs 48 to 72 hours after administration. Various degrees of vomiting, nausea, and/or anorexia may persist for up to 1 week after treatment. Delayed nausea and vomiting (begins or persists 24 hours or more after chemotherapy) has occurred in patients attaining complete emetic control on the day of cisplatin therapy. Consider the use of additional antiemetics following infusion.

Monitor and manage patients with antiemetics or fluid replacement, as clinically indicated. Consider withholding or delaying AXYCIS if nausea or vomiting is severe or intolerable and is not responsive to antiemetics.

Myelosuppression

AXYCIS can cause myelosuppression. Myelosuppression

AXYCIS™
(cisplatin) Injection

Ordering Information

To order AXYCIS (cisplatin) Injection, please contact one of the authorized specialty distributors below:



50 mg /50 mL (1 mg/mL)

NDC: 83831-0158-01

CardinalHealth cencora McKESSON BioCare People who care.

Highlights[1]

- Supplied in multi-dose vials
- No reconstitution required and ready to dilute solution
- Ready to add to intravenous infusion solution with different options:
  - 2 liters of 5% Dextrose in 0.45% Sodium Chloride Injection, containing 37.5 g of mannitol
  - 2 liters of 5% Dextrose in 0.33% Sodium Chloride Injection, containing 37.5 g of mannitol
- Diluted infusion solution is stable for 24 hours when protected from light and for 12 hours under fluorescent light at 20°C to 25°C (68°F to 77°F)
- Partially used vials are stable for 28 days in the original carton at 20°C to 25°C (68°F to 77°F) when protected from light

J-CODE

J9999

Unique J-Code Expected July 2027

Please see Important Safety Information, including **Boxed Warning** on pages 3 and 13 and full Prescribing Information for AXYCIS.

AVYXASSIST®

Simplifying patient access, providing comprehensive support

AVYXASSIST can offer support to qualifying patients in need. The program provides the following services:*

- **Benefit verification**
- **Prior authorization requirements**
- **Appeals support**
- **Claims support**
- **Referrals to 501(c)(3) foundations**
- **Free product assistance**
- **Bridge supply**
- **Product replacement**
- **Copay assistance**

*For eligibility requirements, please contact a Patient Access Specialist. Terms and conditions apply.

To enroll, please choose one of the following options.

Call **866-939-8927** Monday through Friday 8 AM to 8 PM ET

CALL NOW

Click on the link below to begin online enrollment

ENROLL NOW

Download, print, and fax a completed enrollment form to 833-852-3420

DOWNLOAD NOW

Commercially eligible patients prescribed **an AVYXA Pharma, LLC product** may pay as little as

$0 per dose*



Our dedicated AVYXASSIST Patient Access Specialists work collaboratively with you to explore tailored affordability solutions. AVYXA Pharma, LLC aims to facilitate financial accessibility for eligible patients in need.

ENROLL NOW

Copay Program Details for Eligible Patients

In some cases, the patient out-of-pocket cost for their AVYXA Pharma, LLC product could be as low as $0.*

- Up to $25,000 per patient, per drug.

*Please visit **avyxassist.com/copay-assistance-program** to see full Terms and Conditions.

Additional Assistance

Patients without insurance or who do not qualify for copay assistance through AVYXASSIST may qualify for free product assistance. Call an AVYXASSIST Patient Access Specialist to learn more.

Call 866-939-8927 or Fax 833-852-3420 | Monday through Friday, 8:00 AM to 8:00 PM ET

Billing and Coding Information

The information provided is for informational purposes only and represents no statement, promise, or guarantee by AVYXA Pharma, LLC concerning reimbursement, payment, or charges. The information provided is not intended to increase or maximize reimbursement by any payer. Healthcare professionals are responsible for selecting appropriate codes used to file a claim. Codes should be based on the patient's diagnosis and the items and services furnished by the healthcare professional. All codes should be verified between the healthcare professional and the payer. AVYXA Pharma, LLC does not recommend using any particular diagnosis code in billing situations for AXYCIS™ (cisplatin) Injection. The codes below are for reference only; coding as submitted is the sole responsibility of the prescribing physician.

NDC for AXYCIS Injection

Centers for Medicare & Medicaid Services (CMS) and private payers often require an NDC on the billing claim form. The NDC is usually found on the drug label or the medication's outer packaging. Be sure to include the NDC qualifier, 11-digit NDC number, NDC unit of measure, and number of NDC units when submitting claims. If the NDC Package code is fewer than 11 digits, it must be padded with leading zeros, as shown below.[2] The NDC unit of measure for this product is ML.

NDC[1]	Strength	Vial Size
83831-0158-01	**50 mg/50 mL (1 mg/mL)**	**1 multiple-dose vial in 1 carton**

HCPCS Codes

HCPCS Level II codes are used to identify most drugs and biologics administered in an office setting. Correct coding requires reporting the most specific code to describe the service accurately.[3] Not otherwise classified (NOC) and unclassified codes are used only when a more specific HCPCS code is not available or assigned.[4]

AXYCIS Injection J-Code[4]

J-Code	Description
J9999	Not otherwise classified, antineoplastic drugs

For Medicare to properly reimburse unclassified or NOC drugs, providers must include the following supplemental information in the 2400/SV101-7 data element or Item 19 of the CMS-1500 form:

- The name of the drug,
- The total dosage (plus the strength of the dosage, if appropriate), and
- The method of administration.

Some payers may require entering the NDC in Item 19 of the CMS-1500 form. Medicare determines the proper payment for unclassified drugs and biologicals based on the narrative information listed above, not the number of units billed.[5]

Please see Important Safety Information, including **Boxed Warning** on pages 3 and 13 and full Prescribing Information for AXYCIS.

Service Units

Until a permanent J-Code is assigned, AXYCIS™ Injection is often billed using one (1) unit of service.

Important: List one unit of service in the 2400/SV1-04 data element or Item 24G of the CMS-1500 form. Do not quantity-bill unclassified drugs and biologicals even if multiple units of the drug are provided. Claims for unclassified drugs and biologicals may be rejected if any of the information listed above is missing or if the unclassified code is billed with more than one unit of service.[5]

This billing is used in traditional Medicare billing. If you are unsure, check with your payers about their unit requirements.

Modifiers

A medical coding modifier is two characters (letters or numbers) appended to a CPT or HCPCS Level II code. Modifiers provide additional information about the medical procedure or service without changing the definition of the code. Using modifiers allows healthcare providers to designate specific circumstances, such as the route of administration, wasted product, and other relevant details.[6]

AXYCIS is supplied as a multi-dose vial, so no drug waste modifiers - JW, JZ - are required.[7]

340B Drug Pricing Modifier[8]

Modifier	Description
TB	Drug or biological acquired with 340B drug pricing program discount, reported for informational purpose

The "TB" modifier is used for informational purposes to identify drugs purchased through the 340B program. This enables CMS to accurately implement the Part B inflation rebate program established by the Inflation Reduction Act of 2022, as 340B drugs are excluded from the inflation rebate calculation.

CPT Drug Administration Codes

CPT codes bill for drug administration services in the physician's office and other outpatient settings. Administration of AXYCIS varies by indication and usage. Please code based on the start and stop times listed in the patient's medical chart.[9]

AXYCIS dose, frequency, and cycle vary by the specific regimen administered. See package insert.[1]

CPT Code[10]	Description
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
96415	Each additional hour (List separately in addition to code for primary procedure)
96417	Each additional sequential infusion (different substance/drug), up to 1 hour (List separately in addition to code for primary procedure)

CPT codes, descriptions, and other data are copyright 2026 American Medical Association. All Rights Reserved. Applicable FARS/HHSARS apply. Fee schedules, relative value units, conversion factors, and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

Revenue Codes[11]

Claim Item	Revenue Code	Description
AXYCIS™ Infusion	0636	Drugs requiring detailed coding
Drug Administration	0335	Chemotherapy administration - IV

Place of Service (POS) Codes[12]

Place of service (POS) codes are used on professional claims to specify the entity where service(s) are rendered.

Place of Service	Code	Description
Physician Office	11	Location, other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, State or local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis.
Off-Campus Outpatient Hospital	19	A portion of an off-campus hospital provider-based department which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.
On-Campus Outpatient Hospital	22	A portion of a hospital's main campus which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization.

ICD-10-CM Diagnosis Coding

AXYCIS is a platinum-based drug indicated for the treatment of[1]:

- Advanced testicular cancer
- Advanced ovarian cancer
- Advanced bladder cancer

It is best practice to code the most specific ICD-10-CM Code within the indication to justify medical necessity, as documented in the medical record. Check payer policies as guidelines vary.

International Classification of Disease, 10th Edition, Clinical Modification Codes for AXYCIS Injection[13]

Indication	ICD-10-CM Codes
Bladder Cancer	C67.0, C67.1, C67.2, C67.3, C67.4, C67.5, C67.6, C67.7, C67.8, C67.9
Ovarian Cancer	C56.1, C56.2, C56.3, C56.9
Testicular Cancer	C62.00, C62.01, C62.02, C62.10, C62.11, C62.12, C62.90, C62.91, C62.92
Encounter for Chemotherapy	Z51.11

Please see Important Safety Information, including **Boxed Warning** on pages 3 and 13 and full Prescribing Information for AXYCIS.

ICD Diagnosis Codes by Indication

ICD-10-CM coding for AXYCIS™ Injection varies by payer. Please check with each payer to ascertain the best coding for the AXYCIS Injection according to their policy.

Bladder Cancer: ICD-10-CM Diagnosis Coding[13]

ICD-10 Code	Descriptor
C67.0	Malignant neoplasm of trigone of bladder
C67.1	Malignant neoplasm of dome of bladder
C67.2	Malignant neoplasm of lateral wall of bladder
C67.3	Malignant neoplasm of anterior wall of bladder
C67.4	Malignant neoplasm of posterior wall of bladder
C67.5	Malignant neoplasm of bladder neck; Malignant neoplasm of internal bladder orifice
C67.6	Malignant neoplasm of ureteric orifice
C67.7	Malignant neoplasm of urachus
C67.8	Malignant neoplasm of overlapping sites of bladder
C67.9	Malignant neoplasm of bladder, unspecified

Ovarian Cancer: ICD-10-CM Diagnosis Coding[13]

ICD-10 Code	Descriptor
C56.1	Malignant neoplasm of right ovary
C56.2	Malignant neoplasm of left ovary
C56.3	Malignant neoplasm of bilateral ovaries
C56.9	Malignant neoplasm of unspecified ovary

ICD Diagnosis Codes by Indication (continued)

Testicular Cancer: ICD-10-CM Diagnosis Coding[13]

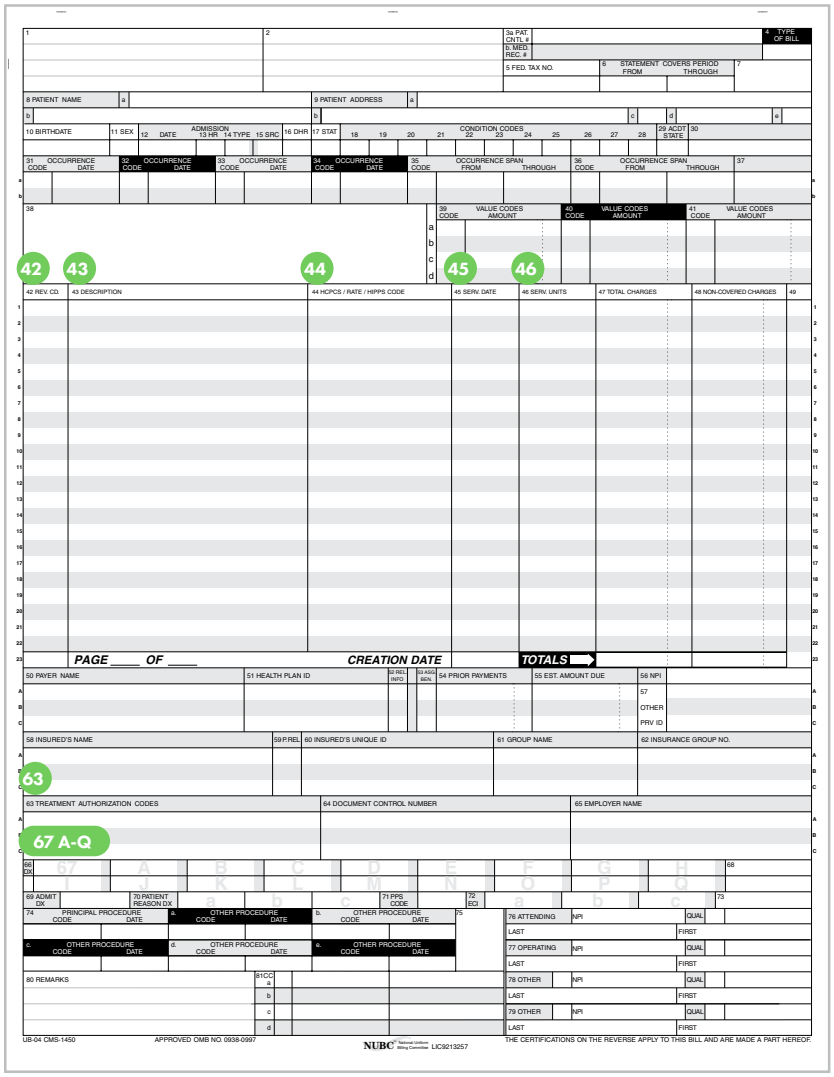
ICD-10 Code	Descriptor
C62.00	Malignant neoplasm of unspecified undescended testis
C62.01	Malignant neoplasm of undescended right testis
C62.02	Malignant neoplasm of undescended left testis
C62.10	Malignant neoplasm of unspecified descended testis
C62.11	Malignant neoplasm of descended right testis
C62.12	Malignant neoplasm of descended left testis
C62.90	Malignant neoplasm of unspecified testis, unspecified whether descended or undescended
C62.91	Malignant neoplasm of right testis, unspecified whether descended or undescended
C62.92	Malignant neoplasm of left testis, unspecified whether descended or undescended

Encounter for Chemotherapy: ICD-10-CM Diagnosis Coding[13]

ICD-10 Code	Descriptor
Z51.11	Encounter for antineoplastic chemotherapy

Please see Important Safety Information, including **Boxed Warning** on pages 3 and 13 and full Prescribing Information for AXYCIS.

Sample Claim Form CMS-1450 (UB-04)[4,10,11,13,14]



Electronic Claims Reference: ASC 837I Version 5010A2 Institutional Health Care Claim to the CMS-1450 Claim Form Crosswalk. Palmettogba.com. Palmetto GBA, Accessed April 3, 2023. https://dominoapps.palmettogba.com/palmetto/providers.nsf/ files/EDI_837I_v5010A2_crosswalk.pdf/$File/EDI_837I_v5010A2_crosswalk.pdf

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Form Locator (FL) 42

(Electronic Claim Form = Loop 2400, Segment Type SV201):

List the appropriate revenue code for the drug. Match the descriptor for AXYCIS™ Injection to your revenue code, 0636-Drugs requiring detailed coding.

Additionally, enter an appropriate revenue code for the administration service, such as 0335 - Chemotherapy administration - IV or others based on the cost center where the service was performed.

FL 43 (NOT REQUIRED BY MEDICARE):

Enter the description of the procedure for the Revenue Code billed.

If required, submit the N4 indicator first, followed by the 11-digit NDC code. Then report the NDC unit of measure code, followed by the quantity. The NDC unit of measure code for AXYCIS is ML.

FL 44 (Electronic Claim Form = Loop 2400, SV202-2) (SV202-1=HC/HP):

Enter the appropriate HCPCS code: ***J9999, Not otherwise classified, antineoplastic drugs.***

For administration, enter the appropriate code or codes for intravenous administration. An example for AXYCIS: 96413. ***Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug.***

AXYCIS dose, frequency, and cycle vary by the specific regimen administered. See package insert.

FL 45 (Electronic Claim Form = Loop 2400, Segment DTP/472/03):

Enter the date of service.

FL 46 (Electronic Claim Form = Loop 2400, SV205):

Enter the units for the billed HCPCS code. Enter the number of service units for each item. For drugs with no assigned J-Code, the service unit is 1.

FL 63 (Electronic Claim Form = Loop 2300,REF/G1/02):

Enter treatment authorization code.

FL 67 A-Q (Electronic Claim Form = Loop 2300, HI01-2) (HI01-1=BK):

Enter a diagnosis code for the drug documented in the medical record. Be as specific as possible.

An example for AXYCIS is: ***Z51.11 Encounter for antineoplastic chemotherapy.***

Use FL 67 C-L fields for other secondary diagnoses.

Sample Claim Form CMS-1500[4,5,10,12,13,15]

Item 19 (Electronic Claim Form = Loop 2400, Segment SV101-2)

Additional claim information

When billing a not otherwise classified or unclassified J-Code, providers must indicate the following:

The name of the drug, total dosage (plus strength of dosage, if appropriate), and method of administration. Some payers may require NDC number here.

Item 21 (Electronic Claim Form = Loop 2300, Segment HI01-2 through HI12=2):

Enter the patient's diagnosis from the patient's medical record.

An example for AXYCIS™ is: ***Z51.11 Encounter for antineoplastic chemotherapy.***

Use Item 21 C-L fields for other secondary diagnoses.

Item 23 (Electronic Claim Form = Loop 2300, REF02):

Enter prior authorization number if one exists.

Item 24 A-B (Electronic Claim Form)

Item 24 A (Electronic Claims = Loop 2400, DTP02)

Item 24 B (Loop 2300/2400, Segment CLM05-1/ SV105)

In the non-shaded area, enter the appropriate date of service and place of service code. Example: Physician Office = 11

If required, in the red shaded portion, submit the N4 indicator first, followed by the 11-digit NDC code. Then, report the NDC unit of measure code followed by the quantity in the same red shaded portion. The NDC unit of measure code for AXYCIS is ML. (Milliliters)

Item 24 D (Electronic Claim Form = Loop 2400, Segment SV101):

Enter the appropriate HCPCS code: ***J9999, Not otherwise classified, antineoplastic drugs.***

For administration, enter the appropriate code or codes for intravenous administration. ***As an example, CPT Code 96413: Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug.***

AXYCIS dose, frequency, and cycle vary by the specific regimen administered and patient age. See package insert.

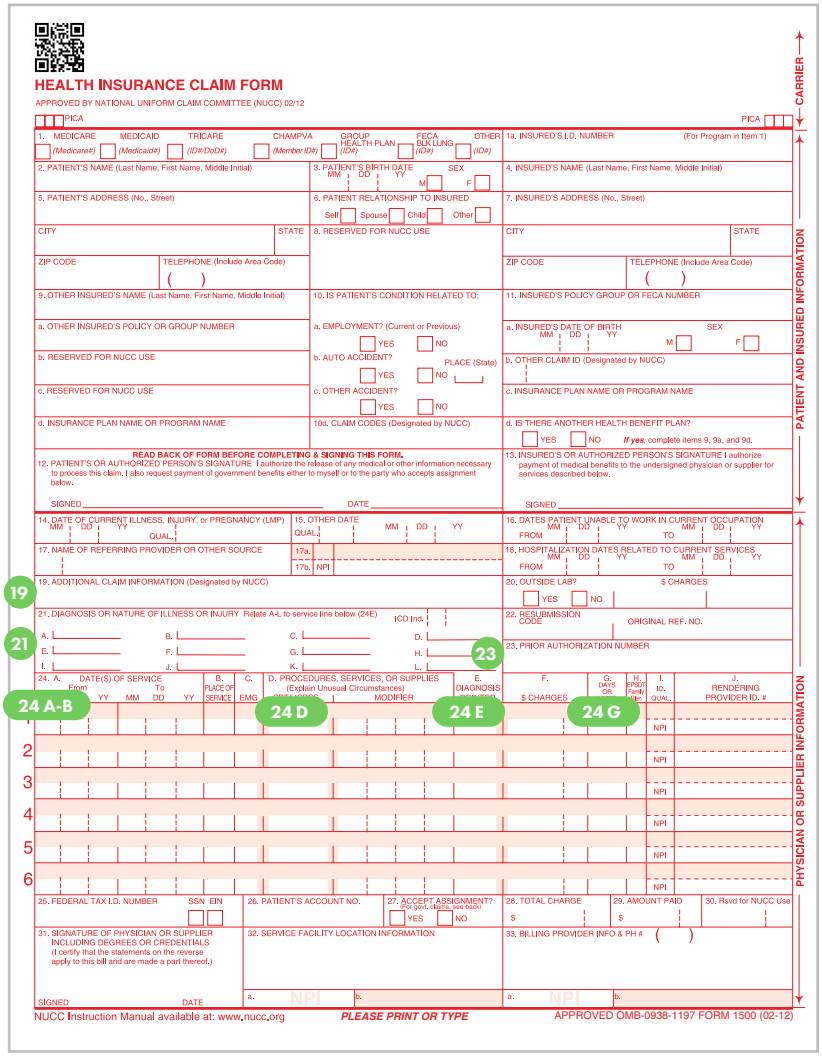
Item 24 E (Electronic Claim Form = Loop 2400, Segment SV107):

Specify the diagnosis letter that corresponds with the drug and drug administration code(s) in Item 21.

Item 24 G (Electronic Claim Form = Loop 2400, SV104):

Enter the number of J-Code service units for each item.

For drugs with no assigned J-Code, the service unit is 1. Check with individual payers regarding guidelines for service units.



Electronic Claims Reference: ASC 837I Version 5010A2 Institutional Health Care Claim to the CMS-1450 Claim Form Crosswalk. Palmettogba.com. Palmetto GBA, Accessed April 3, 2023. https://dominoapps.palmettogba.com/palmetto/providers.nsf/ files/EDI_837I_v5010A2_crosswalk.pdf/$File/EDI_837I_v5010A2_crosswalk.pdf

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IMPORTANT SAFETY INFORMATION (continued)

occurs in 25% to 30% of patients treated with cisplatin, including febrile neutropenia and infection, and can be fatal. Fatalities due to infection (secondary to myelosuppression) have been reported. Geriatric patients may be more susceptible to myelosuppression.

Patients with impaired kidney function are at increased risk of severe myelosuppression and may require dosage modifications.

Monitor complete blood counts prior to each cycle and as clinically indicated. If myelosuppression occurs, modify AXYCIS dosage when required.

Hypersensitivity Reactions

AXYCIS can cause severe hypersensitivity reactions, including anaphylaxis and death. Hypersensitivity reactions included facial edema, wheezing, tachycardia, and hypotension. These adverse reactions may occur within minutes of administration and during any cycle.

Monitor patients receiving AXYCIS for hypersensitivity reactions. Ensure supportive equipment and medications are available to treat severe hypersensitivity reactions. Severe hypersensitivity reactions require immediate discontinuation of AXYCIS and aggressive therapy. Do not rechallenge patients with a history of severe hypersensitivity reactions with AXYCIS. Cross-reactivity between platinum-based antineoplastic agents has been reported. Cases of severe hypersensitivity reactions have recurred after rechallenging patients with a different platinum agent.

Ototoxicity

AXYCIS can cause ototoxicity, which is cumulative and may be severe. Monitor for signs and symptoms of ototoxicity and consider audiometric and vestibular function monitoring.

Ototoxicity is manifested by tinnitus, hearing loss in the high frequency range (4,000 to 8,000 Hz) and/or decreased ability to hear normal conversational tones, and vestibular toxicity. Ototoxicity can occur during or after treatment and can be unilateral or bilateral. Deafness after the initial dose of cisplatin has been reported.

Ototoxic effects can be more severe and detrimental in pediatric patients, particularly in patients less than 5 years of age. The prevalence of hearing loss in pediatric patients is estimated to be 40-60%. Additional risk factors for ototoxicity include simultaneous cranial irradiation, treatment with other ototoxic drugs and renal impairment. Consider audiometric and vestibular testing in all pediatric patients receiving cisplatin. Genetic factors (e.g. variants in the thiopurine S-methyltransferase [TPMT] gene) may also contribute to the cisplatin-induced ototoxicity; this association has not been consistent across populations and study designs.

Consider permanent discontinuation of AXYCIS for patients who develop ototoxicity.

Ocular Toxicity

AXYCIS can cause ocular toxicity including optic neuritis, papilledema, and cortical blindness. Blurred vision and altered color perception have been reported after the use of regimens with higher doses and dose frequencies of cisplatin. The altered color perception manifests as a loss of color discrimination, particularly in the blue-yellow axis and irregular retinal pigmentation of the macular area on fundoscopic exam. Improvement and/or total recovery usually occurs after discontinuing AXYCIS but can be delayed.

Monitor for signs and symptoms of ocular toxicity. Promptly refer patients to an eye care provider for any new or worsening ocular signs and symptoms. Interrupt, reduce the dose, or permanently discontinue AXYCIS based on severity.

Secondary Malignancies

Secondary acute leukemia has occurred with use of cisplatin.

Embryo-Fetal Toxicity

Based on human data, AXYCIS can cause fetal harm when administered to a pregnant woman. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment and for 14 months after the last dose of AXYCIS. Advise male patients with female partners of reproductive potential to use effective contraception during treatment and for 11 months after the last dose of AXYCIS.

Injection Site Reactions

Injection site reactions can occur during the administration of AXYCIS. Local soft tissue toxicity has been reported following extravasation of AXYCIS. Severity of the local tissue toxicity appears to be related to the concentration of the AXYCIS solution. Infusion of solutions with a cisplatin concentration greater than 0.5 mg/mL may result in tissue cellulitis, fibrosis, necrosis, pain, edema, and erythema.

Monitor patients for extravasation and advise patients to seek medical care for progression of symptoms.

ADVERSE REACTIONS

Common adverse reactions are nephrotoxicity, peripheral neuropathy, nausea and vomiting, myelosuppression, and ototoxicity.

DRUG INTERACTIONS

Drugs that Cause Nephrotoxicity

Avoid concomitant use with other products known to cause nephrotoxicity.

IMPORTANT SAFETY INFORMATION (continued)

Cisplatin can cause nephrotoxicity. Concomitant use of AXYCIS with other products that cause nephrotoxicity may result in a greater risk of nephrotoxicity.

USE IN SPECIFIC POPULATIONS

Pregnancy

Based on human data from published literature, AXYCIS can cause fetal harm when administered to pregnant women. Data demonstrates transplacental transfer of cisplatin. Exposure of pregnant women to cisplatin-containing chemotherapy has been associated with oligohydramnios, intrauterine growth restriction, and preterm birth. Cases of neonatal acute respiratory distress syndrome, cytopenias, and hearing loss have been reported.

Advise pregnant women and females of reproductive potential of the potential risk to a fetus.

Lactation

Limited data from published literature report the presence of cisplatin in human milk in low amounts. Because of the potential for serious adverse reactions from cisplatin in a breastfed child and because of the potential for tumorigenicity shown for cisplatin, advise lactating women not to breastfeed during treatment with AXYCIS.

Females and Males of Reproductive Potential

AXYCIS can cause fetal harm when administered to a pregnant woman.

Pregnancy Testing

Verify the pregnancy status of females of reproductive potential prior to initiation of AXYCIS.

Contraception

Advise females of reproductive potential to use effective contraception during treatment and for 14 months following the last dose of AXYCIS. Advise male patients with female partners of reproductive potential to use effective contraception during treatment and for 11 months after the last dose of AXYCIS.

Infertility

The use of cisplatin in females has been associated with cumulative dose-dependent ovarian failure, premature menopause, and reduced fertility. The use of cisplatin in males has been associated with a cumulative dose-dependent impairment of spermatogenesis (oligospermia, azoospermia; possibly irreversible) and reduced fertility.

Pediatric Use

The safety and effectiveness of AXYCIS in pediatric patients have not been established.

Ototoxic effects may be more severe and detrimental in pediatric patients receiving cisplatin, particularly in patients less than 5 years of age. Consider audiometric and vestibular function monitoring in all patients receiving AXYCIS. The prevalence of hearing loss in pediatric patients is particularly high and is estimated to be 40% to 60%. Earlier detection of hearing loss can limit the potential impact of hearing impairment on a pediatric patient's cognitive and social development.

Geriatric Use

Reported clinical experience suggests that geriatric patients may be more susceptible to nephrotoxicity, myelosuppression, and infectious complications than are younger patients.

OVERDOSAGE

The signs and symptoms of overdose are similar to known adverse reactions of cisplatin but may be more severe. Acute overdosage with AXYCIS may result in renal failure, hepatic failure, hearing loss, ocular toxicity, myelosuppression, nausea and vomiting, and neuritis. In addition, death can occur following overdosage.

Important measures include renal protection by intravenous hydration with or without the use of an osmotic diuretic. Hemodialysis is not effective because of the high degree of protein binding of cisplatin. Plasmapheresis has been used to treat cases of cisplatin overdosage, but the optimal treatment regimen has not been established.

Closely monitor patients suspected of receiving an overdose, including signs and symptoms of the adverse reactions and administer appropriate supportive treatment.

Consider contacting the Poison Help line (1-800-222-1222) or a medical toxicologist for additional overdose management recommendations.

DOSAGE AND ADMINISTRATION GUIDELINES

It is very important that the dosage, preparation and administration instructions provided in the full prescribing information are strictly followed to reduce the risk of severe adverse reactions.

Please see AXYCIS full Prescribing Information, including BOXED WARNING.

To report SUSPECTED ADVERSE REACTIONS, contact AVYXA Pharma, LLC at 1-888-520-0954 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

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AXYCIS™
(cisplatin) Injection



50 mg /50 mL (1 mg/mL)

NDC: 83831-0158-01

AVYXA Pharma, LLC offers resources to help your patients start and stay on prescribed therapy. We are dedicated to providing your patients with ongoing support to help them access AVYXA Pharma, LLC medications as prescribed.

Contact your Account Manager to connect with a Field Reimbursement Manager for the latest payer coverage for patients and assistance with billing and coding.

Please see Important Safety Information, including **Boxed Warning** on pages 3 and 13 and full Prescribing Information for AXYCIS.

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