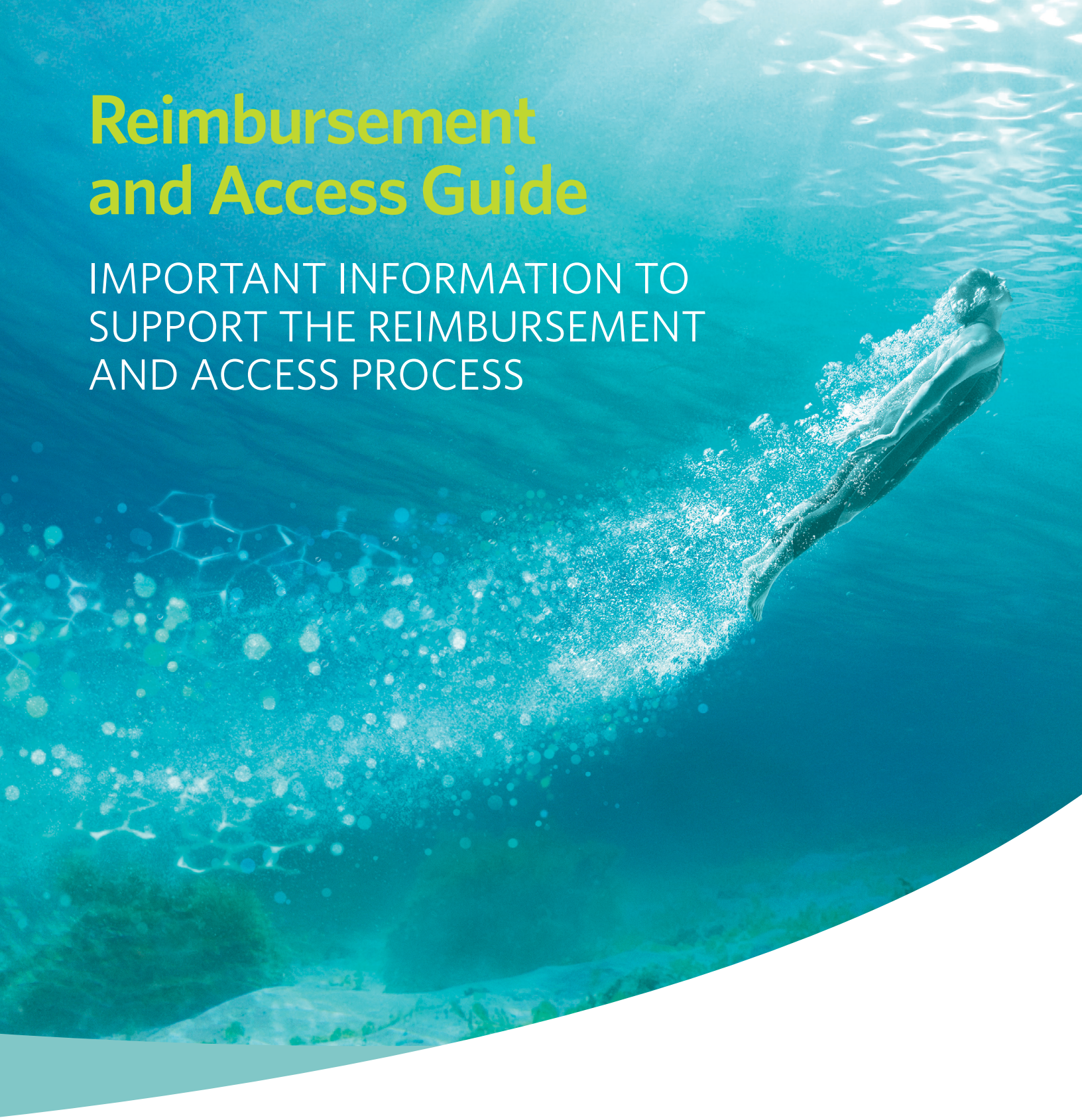
Reimbursement and Access Guide

IMPORTANT INFORMATION TO SUPPORT THE REIMBURSEMENT AND ACCESS PROCESS



Janssen Oncology
PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Pharma Mar

Yondelis® (trabectedin)

Janssen Products, LP, is pleased to provide you and your office staff with detailed information to assist you in obtaining reimbursement for YONDELIS® (trabectedin) Injection on behalf of your patients. We have developed this Reimbursement and Access Guide to provide coding information, a list of specialty distributors, and important product information that we hope will be helpful to you and your practice as you support your patients prescribed YONDELIS®.

Janssen CarePath

Call **877-CarePath** (877-227-3728)
Monday–Friday, 8:00 AM–8:00 PM ET

Sign Up or Log In to the Provider Portal at **JanssenCarePathPortal.com**

Visit us online
JanssenCarePath.com

At Janssen CarePath, we're committed to helping you get your patients started on the Janssen medications they may need, finding financial assistance options, and providing ongoing support to help them stay on prescribed therapy. Janssen CarePath can provide the following support for your patients: conduct benefits investigations, provide Prior Authorization support if needed, review and explain insurance coverage information and out-of-pocket cost for the medication, help identify financial assistance options, and support them with a dedicated Care Coordinator and educational resources.

We appreciate your interest in YONDELIS®. Please feel free to call 877-CarePath (877-227-3728) to speak with a Janssen CarePath Care Coordinator if you have any questions.

- This document is presented for informational purposes only and is not intended to provide reimbursement or legal advice
- Laws, regulations, and policies concerning reimbursement are complex and are updated frequently
  - While we have made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it
  - Similarly, all Current Procedural Terminology (CPT®) and Healthcare Common Procedure Coding System (HCPCS) codes are supplied for informational purposes only, and this information does not represent any statement, promise, or guarantee by Janssen Products, LP, about coverage, levels of reimbursement, payment, or charge
- Please consult with your payer organization(s) for local or actual coverage and reimbursement policies and with your internal reimbursement specialist for any reimbursement or billing questions*

Before prescribing YONDELIS®, please click here to see full Prescribing Information.

TABLE OF CONTENTS

YONDELIS® (trabectedin) INDICATION, DOSING, AND ADMINISTRATION

Indication[1]

- YONDELIS® (trabectedin) is indicated for the treatment of patients with unresectable or metastatic liposarcoma or leiomyosarcoma who received a prior anthracycline-containing regimen.

YONDELIS® Is Given Over 24 Hours by Infusion[1]

- Recommended dosing: 1.5 mg/m^2 administered as an intravenous infusion over 24 hours through a central venous line every 21 days (3 weeks), until disease progression or unacceptable toxicity
- Hepatic impairment: The recommended dose is 0.9 mg/m^2 in patients with moderate hepatic impairment (bilirubin levels greater than 1.5 times to 3 times the upper limit of normal, and AST and ALT less than 8 times the upper limit of normal). Do not administer YONDELIS® to patients with severe hepatic impairment (bilirubin levels above 3 times the upper limit of normal, and any AST and ALT)
- Premedication: administer dexamethasone 20 mg intravenously 30 minutes prior to each dose of YONDELIS®
- Administer YONDELIS® reconstituted, diluted solution through a central venous line using an infusion set with a 0.2-micron polyethersulfone (PES) in-line filter to reduce the risk of exposure to adventitious pathogens that may be introduced during solution preparation
- Complete infusion within 30 hours of initial reconstitution. Discard any unused portion of the reconstituted product or of the infusion solution
- Please click here to see the full Prescribing Information for complete dosing and administration, including preparation

AST = aspartate aminotransferase; ALT = alanine aminotransferase.

CONTRAINDICATIONS

YONDELIS® is contraindicated in patients with known severe hypersensitivity, including anaphylaxis, to trabectedin.

Please read Important Safety Information on pages 24-25.

Click here to read the full Prescribing Information for Yondelis®.

YONDELIS® (trabectedin) DOSING AND ADMINISTRATION (cont'd)

Dose Modifications[1]

Permanently discontinue YONDELIS® for:

- Persistent adverse reactions requiring a delay in dosing of more than 3 weeks
- Adverse reactions requiring dose reduction following YONDELIS® administered at 1.0 mg/m^2 for patients with normal hepatic function or at 0.3 mg/m^2 for patients with pre-existing moderate hepatic impairment
- Severe liver dysfunction: bilirubin 2 times the upper limit of normal and AST or ALT 3 times the upper limit of normal with ALP less than 2 times the upper limit of normal in the prior treatment cycle for patients with normal liver function at baseline
- Exacerbation of liver dysfunction in patients with pre-existing moderate hepatic impairment
- Capillary leak syndrome
- Rhabdomyolysis
- Grade 3 or 4 cardiac adverse events (AEs) indicative of cardiomyopathy or for subjects with an LVEF that decreases below the lower limit of normal

Recommended Dose Modifications for Adverse Reactions

The recommended dose modifications for adverse reactions are listed in Table 1. Once reduced, the dose of YONDELIS® should not be increased in subsequent treatment cycles.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Hepatotoxicity, including hepatic failure, can occur. Patients with serum bilirubin levels above the upper limit of normal or AST or ALT levels >2.5 x upper limit of normal were not enrolled in Trial ET743-SAR-3007. In Trial ET743-SAR-3007, the incidence of Grade 3-4 elevated liver function tests (defined as elevations in ALT, AST, total bilirubin, or alkaline phosphatase) was 35% (134/378) in patients receiving YONDELIS®. Median time to development of Grade 3-4 elevation in ALT or AST was 29 days (range: 3 days to 11.5 months). Of the 134 patients with Grade 3 to 4 elevations in LFTs, 114 (85%) experienced complete resolution with the median time to complete resolution of 13 days (range: 4 days to 4.4 months). In Trial ET743-SAR-3007, the incidence of drug-induced liver injury (defined as concurrent elevation in ALT or AST of more than three times the upper limit of normal, alkaline phosphatase less than two times the upper limit of normal, and total bilirubin at least two times the upper limit of normal) was 1.3% (5/378) in patients receiving YONDELIS®. ALT or AST elevation greater than eight times the upper limit of normal occurred in 18% (67/378) of patients receiving YONDELIS®. Assess LFTs prior to each administration of YONDELIS® and as clinically indicated based on underlying severity of pre-existing hepatic impairment. Manage elevated LFTs with treatment interruption, dose reduction, or permanent discontinuation based on severity and duration of LFT abnormality.

Please read Important Safety Information on pages 24-25.
Click here to read the full Prescribing Information for Yondelis®.

YONDELIS® (trabectedin) DOSING AND ADMINISTRATION (cont'd)

Table 1: Recommended Dose Modification[1]

Laboratory Result or Adverse Reaction	DELAY next dose of YONDELIS® for up to 3 weeks	REDUCE next dose of YONDELIS® by one dose level for adverse reaction(s) during prior cycle
Platelets	Less than 100,000 platelets/ microliter	Less than 25,000 platelets/microliter
Absolute neutrophil count	Less than 1,500 neutrophils/ microliter	• Less than 1,000 neutrophils/microliter with fever/infection • Less than 500 neutrophils/microliter lasting more than 5 days
Total bilirubin	Greater than the upper limit of normal	Greater than the upper limit of normal
Aspartate aminotransferase or alanine aminotransferase	More than 2.5 times the upper limit of normal	More than 5 times the upper limit of normal
Alkaline phosphatase	More than 2.5 times the upper limit of normal	More than 2.5 times the upper limit of normal
Creatine phosphokinase	More than 2.5 times the upper limit of normal	More than 5 times the upper limit of normal
Other non-hematologic adverse reactions	Grade 3 or 4	Grade 3 or 4

Please read Important Safety Information on pages 24-25.

Click here to read the full Prescribing Information for Yondelis®.

YONDELIS® (trabectedin) DOSING AND ADMINISTRATION (cont'd)

The recommended starting doses and dose reductions for YONDELIS® are shown in Table 2.

Table 2: Recommended Starting Doses and Dose Reductions

Starting Dose and Dose Reduction	For patients with normal hepatic function or mild hepatic impairment* prior to initiation of YONDELIS® treatment	For patients with moderate hepatic impairment† prior to initiation of YONDELIS® treatment
Starting Dose	1.5 mg/m^2	0.9 mg/m^2
Dose Reduction		
First dose reduction	1.2 mg/m^2	0.6 mg/m^2
Second dose reduction	1.0 mg/m^2	0.3 mg/m^2

*Including patients with bilirubin greater than 1 to 1.5 times the upper limit of normal and any AST or ALT.

†Including patients with bilirubin levels greater than 1.5 times to 3 times the upper limit of normal and AST and ALT less than 8 times the upper limit of normal.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Neutropenic sepsis, including fatal cases, can occur. In Trial ET743-SAR-3007, the incidence of Grade 3 or 4 neutropenia, based on laboratory values, was 43% (161/378). Median time to the first occurrence of Grade 3 or 4 neutropenia was 16 days (range: 8 days to 9.7 months). Median time to complete resolution of neutropenia was 13 days (range: 3 days to 2.3 months). Febrile neutropenia (fever ≥38.5°C with Grade 3 or 4 neutropenia) occurred in 18 patients (5%) treated with YONDELIS®. Ten patients (2.6%) experienced neutropenic sepsis, 5 of whom had febrile neutropenia, which was fatal in 4 patients (1.1%). Assess neutrophil count prior to administration of each dose of YONDELIS® and periodically throughout the treatment cycle. Withhold or reduce dose of YONDELIS® based on severity of adverse reaction.

Please read Important Safety Information on pages 24-25.

Click here to read the full Prescribing Information for Yondelis®.

FACTORS THAT MAY INFLUENCE COVERAGE

Third-party payers, both public (eg, Medicare and Medicaid) and commercial (eg, private, employer-sponsored) plans will commonly cover drugs administered for their approved US Food and Drug Administration (FDA) indications. Individual benefits and coverage rules, however, can vary by insurance type, as well as by the specific product prescribed to a patient. Here are some considerations:

- Payer type: public payer, commercial plan
- Insurance product: Preferred Provider Organization (PPO), Health Maintenance Organization (HMO), etc
- Provider participation: in network or out of network
- Site of care (SOC): preferred or restricted care settings
- Approval requirements: preauthorization, primary care/other referral

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

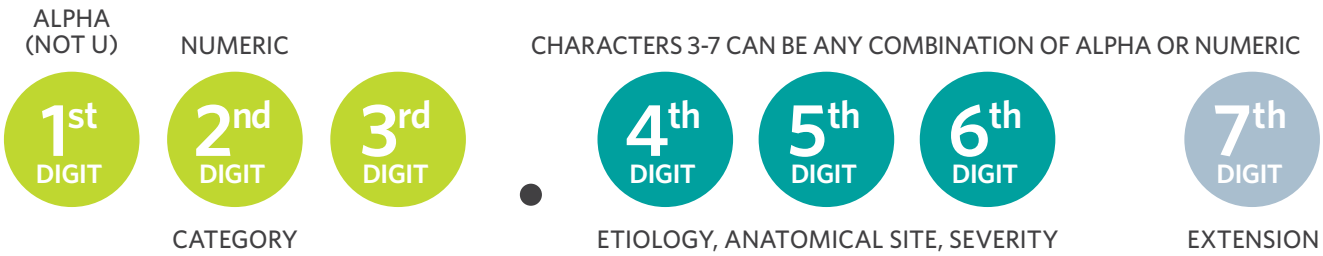
Rhabdomyolysis — YONDELIS® can cause rhabdomyolysis and musculoskeletal toxicity. In Trial ET743-SAR-3007, rhabdomyolysis leading to death occurred in 3 (0.8%) of the 378 patients receiving YONDELIS®. Elevations in creatine phosphokinase (CPK) occurred in 122 (32%) of the 378 patients receiving YONDELIS®, including Grade 3 or 4 CPK elevation in 24 patients (6%), compared to 15 (9%) of the 172 patients receiving dacarbazine with any CPK elevation, including 1 patient (0.6%) with Grade 3 CPK elevation. Among the 24 patients receiving YONDELIS® with Grade 3 or 4 CPK elevation, renal failure occurred in 11 patients (2.9%); rhabdomyolysis with the complication of renal failure occurred in 4 of these 11 patients (1.1%). Median time to first occurrence of Grade 3 or 4 CPK elevations was 2 months (range: 1 to 11.5 months). Median time to complete resolution was 14 days (range: 5 days to 1 month). Assess CPK levels prior to each administration of YONDELIS®. Withhold, reduce dose, or permanently discontinue based on severity of adverse reaction.

Please read Important Safety Information on pages 24-25.
Click here to read the full Prescribing Information for Yondelis®.

CODING FOR YONDELIS® (trabectedin)

ICD-10-CM Diagnosis Codes[2]

All parties covered by HIPAA, not just providers who bill Medicare or Medicaid, are required to use the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) codes to document patient diagnoses. ICD-10-CM far exceeds previous coding systems in the number of concepts and codes provided, allowing for greater specificity when describing patient conditions. ICD-10-CM uses 3-7 alpha and numeric digits to achieve this level of detail:



Codes with three characters are included in ICD-10-CM as the heading of a category of codes that may be further subdivided by the use of any or all of the 4th, 5th, and 6th characters. Digits 4-6 provide greater detail of etiology, anatomical site, and severity. For example:

- C49 Malignant neoplasms of other connective and soft tissue
- C49.1 Malignant neoplasm of connective and soft tissue of upper limb, including shoulder
- C49.10 Malignant neoplasm of connective and soft tissue of unspecified upper limb, including shoulder

CODING FOR YONDELIS® (trabectedin) (cont'd)

ICD-10-CM Diagnosis Codes[2] (cont'd)

It is not necessary to use all 7 digits, however coding to the highest level of specificity is required. The ICD-10-CM codes for the labeled indication for YONDELIS® are listed in the following chart:

ICD-10 Codes for YONDELIS®[3]
C49 – Malignant neoplasm of other connective and soft tissue
C49.0 – Malignant neoplasm of connective and soft tissue of head, face and neck
C49.1 – Malignant neoplasm of connective and soft tissue of upper limb, including shoulder
C49.2 – Malignant neoplasm of connective and soft tissue of lower limb, including hip
C49.3 – Malignant neoplasm of connective and soft tissue of thorax
C49.4 – Malignant neoplasm of connective and soft tissue of abdomen
C49.5 – Malignant neoplasm of connective and soft tissue of pelvis
C49.6 – Malignant neoplasm of connective and soft tissue of trunk, unspecified
C49.8 – Malignant neoplasm of overlapping sites of connective and soft tissue
C49.9 – Malignant neoplasm of connective and soft tissue, unspecified

Note: These codes are not intended to be promotional, or to encourage or suggest a use of drug that is inconsistent with FDA-approved use. Please refer to the current policy for the latest codes since these codes are subject to change. The codes provided are not intended to be exhaustive and may require a higher level of specificity. The ultimate responsibility for correct coding lies with the provider of services and must be supported with detailed documentation in the medical record. Please consult your ICD-10 coding resources for additional information.

Please read Important Safety Information on pages 24-25.

Click here to read the full Prescribing Information for Yondelis®.

CODING FOR YONDELIS® (trabectedin) (cont'd)

National Drug Code (NDC)

NDC for YONDELIS®[1]		
10-digit NDC	11-digit NDC	Description
59676-610-01	59676-0610-01	Single-use vial containing 1 mg of trabectedin lyophilized powder

Payer requirements regarding the use of the 10- or 11-digit NDC may vary. Electronic data exchange generally requires use of the 11-digit NDC. To convert the 10-digit format to the 11-digit format, insert a leading zero into the middle sequence, as illustrated above. It may be necessary to include the NDC on claims along with the drug HCPCS codes. Payer requirements for NDC use and format may vary and should be verified with the payer. For additional information please see "Billing With National Drug Codes (NDCs)" in Appendix A in this guide.

Coding the Drug

Medicare Administrative Contractors (MACs), many private payers, and most Medicaid agencies require healthcare providers to use Healthcare Common Procedure Coding System (HCPCS) codes to identify infused drugs on claim forms. YONDELIS® is identified with a permanent, drug-specific HCPCS code that should be used on claim forms submitted from either the physician office or hospital outpatient sites of care:

Permanent Code	Descriptor	Medicare Physician Office Claims	Medicare HOPD Claims	Non-Medicare Payer Claims
J9352[4]	Injection, trabectedin, 0.1 mg[4]	✓	✓	✓

CODING FOR YONDELIS® (trabectedin) (cont'd)

Billing YONDELIS® in HCPCS Units

The permanent HCPCS code for YONDELIS® is J9352, described as "injection, trabectedin, 0.1 mg". Each 0.1-mg dose is equal to one HCPCS unit. When billing YONDELIS® it is necessary to express the billed amounts in HCPCS units, not milligrams. The following chart illustrates the correlation between vials, milligrams and units:

Number of vials	Number of mg in vial	Number of HCPCS units J9352 – Injection, trabectedin, 0.1 mg
1	1	10

For example, if a patient receives a 3-mg dose of YONDELIS®, the correct claim entry is 30 units:

Required dose	Number of vials	Number of HCPCS units J9352 – Injection, trabectedin, 0.1 mg
3 mg	3	30

Please consult with your local payer or contact Janssen CarePath at 877-CarePath (877-227-3728).

Please read Important Safety Information on pages 24-25.

Click here to read the full Prescribing Information for Yondelis®.

CODING FOR YONDELIS® (trabectedin) (cont'd)

Coding Drug Administration

Medicare policy regarding prolonged drug and biological infusions that are started incident to a physician's service using an external infusion pump, should be billed to the A/B MAC in both the outpatient hospital[5] and physician office[6] settings. To report extended chemotherapy intravenous infusions via pump, CMS has assigned a G code and instructed Medicare Administrative Contractors to implement its use:

Code	Short Descriptor	Long Descriptor
G0498[4]	Chemo extend IV infus w/pump[4]	Chemotherapy administration, intravenous infusion technique; initiation of infusion in the office/other outpatient setting using office/other outpatient setting pump/supplies, with continuation of the infusion in the community setting (eg, home domiciliary, rest home or assisted living) using a portable pump provided by the office/other outpatient setting, includes follow-up office/other outpatient visit at the conclusion of the infusion[4]

Codes that may apply to the administration of YONDELIS® include:

Potential Codes for YONDELIS® Administration[4,7]				
Code	Descriptor	Medicare Physician Office Claims	Medicare HOPD Claims	Non-Medicare Payer Claims
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug	N/A	✓	✓
96415	Each additional hour (List separately in addition to code for primary procedure)	N/A	✓	✓
G0498*	Chemo extend IV infus w/pump	✓	✓	verify with payer
96416†	Initiation of prolonged chemotherapy infusion (more than 8 hours), requiring use of a portable or implantable pump	N/A	N/A	verify with payer

*G0498 must be reported on Medicare claims. Use of this code by non-Medicare payers may vary.
†96416 should not be reported on Medicare claims. Other payer requirements may vary.

YONDELIS® (trabectedin) ADMINISTRATION SCENARIOS

These site-of-care scenarios and sample claim forms for the administration of YONDELIS® provide information on potential coding that may be considered for claims submission in various sites of care:

- **Physician Practice Initiation of Prolonged Chemotherapy Infusion**
- **Hospital Outpatient Initiation of Prolonged Chemotherapy Infusion**
- **Hospital Outpatient Administration of Chemotherapy Infusion**

The scenarios are presented for informational purposes only, and are not intended to provide reimbursement or legal advice.

The information provided represents no statement or guarantee of Janssen Products, LP, concerning levels of reimbursement, payment, or charge. Please consult your payer with regard to local or actual coverage, reimbursement policies, and determination process.

Please read Important Safety Information on pages 24-25.

Click here to read the full Prescribing Information for Yondelis®.

YONDELIS® (trabectedin) ADMINISTRATION:

Physician Practice Initiation of Prolonged Chemotherapy Infusion

Scenario: The drug infusion is started in the physician office setting using an external pump. The patient is then sent home for the remainder of the infusion and returns at the end of the infusion period.

Claim Form	Codes/Descriptors	Units/ Instructions	Medicare Claims	Non-Medicare Payer Claims
CMS 1500	**G0498*** – Chemo extend IV infus w/pump	1 - Includes pump, supplies; do not bill additional codes	✓	verify with payer
	96416† – Initiation of prolonged chemotherapy infusion (more than 8 hours), requiring use of a portable or implantable pump	1 - Pump and supplies may be billed separately	N/A	verify with payer
	J9352 – Injection, trabectedin, 0.1 mg	0.1 mg = 1 unit Report dose in units	✓	✓

*G0498 is considered all-inclusive for the chemotherapy administration, the pump, supplies and follow-up visit at the conclusion of the infusion. Do not report additional codes or charges. Use of this code by non-Medicare payers may vary.

†96416 should not be reported on Medicare claims. Other payer requirements may vary.

Please consult with your local payer or contact Janssen CarePath at 877-CarePath (877-227-3728).

The following sample claim illustrates this scenario. ▶

YONDELIS® (trabectedin) ADMINISTRATION:

Physician Practice Initiation of Prolonged Chemotherapy Infusion

Physician Office Sample Claim Form: CMS-1500

1. **Item 21**—Indicate diagnosis using appropriate ICD-10-CM codes. Use diagnosis codes to the highest level of specificity for the date of service and enter them in priority order. The "ICD Indicator" identifies the ICD code set being reported. For ICD-10-CM diagnoses, enter 0 (zero) as a single digit between the vertical, dotted lines.

2. **Item 24B**—Indicate appropriate place of service (POS) code.
   - Physician office – 11
   - On-campus, outpatient, provider-based department of a hospital – 22
   - Off-campus, outpatient, provider-based department of a hospital – 19

3. **Item 24D**—Indicate appropriate CPT and HCPCS codes and modifiers, if required.

   YONDELIS®
   - HCPCS code J9352 – Injection, trabectedin, 0.1 mg

   Drug Administration
   - Medicare claims: G0498 (Chemo extend IV infus w/pump) is required. Do not bill additional codes for the pump or supplies
   - Non-Medicare claims: Payer requirements may vary

   Please consult with your local payer or contact Janssen CarePath at 877-CarePath (877-227-3728) to confirm payer requirements.

4. **Item 24E**—Refer to the diagnosis for this service (see Item 21). Enter only one diagnosis pointer per line.

5. **Item 24F**—Indicate total charges.

6. **Item 24G**—Enter the amount of drug in HCPCS units:
   - Bill 1 unit for every 0.1 mg of YONDELIS® (10 units contained in each 1-mg vial)

YONDELIS® (trabectedin) ADMINISTRATION:

Physician Practice Initiation of Prolonged Chemotherapy Infusion

CMS-1500 Sample Claim Form

HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE	MEDICAID	TRICARE	CHAMPVA	GROUP HEALTH PLAN	FECA BLK LUNG	OTHER
[X] (Medicare#)	[ ] (Medicaid#)	[ ] (ID#/DoD#)	[ ] (Member ID#)	[ ] (ID#)	[ ] (ID#)	[ ] (ID#)

CARRIER

PATIENT AND INSURED INFORMATION

1a. INSURED'S I.D. NUMBER (For Program in Item 1): 000-00-1234		
2. PATIENT'S NAME (Last Name, First Name, Middle Initial): Doe, John B.	3. PATIENT'S BIRTH DATE: 07 01 45 SEX: M [X] F [ ]	4. INSURED'S NAME (Last Name, First Name, Middle Initial): Doe, John B.
5. PATIENT'S ADDRESS (No., Street): 3914 Spruce Street	6. PATIENT RELATIONSHIP TO INSURED: Self [X] Spouse [ ] Child [ ] Other [ ]	7. INSURED'S ADDRESS (No., Street): 3914 Spruce Street
CITY: Anytown STATE: AS	8. RESERVED FOR NUCC USE	CITY: Anytown STATE: AS
ZIP CODE: 01010 TELEPHONE (Include Area Code): (203) 555-1234		ZIP CODE: 01010 TELEPHONE (Include Area Code): (203) 555-1234
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)	10. IS PATIENT'S CONDITION RELATED TO:	11. INSURED'S POLICY GROUP OR FECA NUMBER
a. OTHER INSURED'S POLICY OR GROUP NUMBER	a. EMPLOYMENT? (Current or Previous) [ ] YES [ ] NO	a. INSURED'S DATE OF BIRTH MM DD YY SEX M [ ] F [ ]
b. RESERVED FOR NUCC USE	b. AUTO ACCIDENT? [ ] YES [ ] NO PLACE (State)	b. OTHER CLAIM ID (Designated by NUCC)
c. RESERVED FOR NUCC USE	c. OTHER ACCIDENT? [ ] YES [ ] NO	c. INSURANCE PLAN NAME OR PROGRAM NAME
d. INSURANCE PLAN NAME OR PROGRAM NAME: Medicare	10d. CLAIM CODES (Designated by NUCC)	d. IS THERE ANOTHER HEALTH BENEFIT PLAN? [ ] YES [ ] NO *If yes*, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.
SIGNED _____ DATE _____

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.
SIGNED _____

PHYSICIAN OR SUPPLIER INFORMATION

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.	15. OTHER DATE QUAL. MM DD YY	16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM TO MM DD YY
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE: Dr. Jones	17a. 17b. NPI 123 456 7890	18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO MM DD YY
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)		20. OUTSIDE LAB? [ ] YES [ ] NO $ CHARGES
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind. 0 A. C49.9 B. C. D. E. 1 F. 2 G. H. I. J. K. L.		22. RESUBMISSION CODE ORIGINAL REF. NO. 23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1	01 01 18	01 01 18	11		J9352		A	6	30		NPI	123 456 7890
2	01 01 18	01 01 18	11	3	G0498		A		1		NPI	123 456 7890
3					4						NPI	
4											NPI	
5											NPI	
6											NPI	

25. FEDERAL TAX I.D. NUMBER SSN EIN	26. PATIENT'S ACCOUNT NO.	27. ACCEPT ASSIGNMENT? (For govt. claims, see back) [ ] YES [ ] NO	28. TOTAL CHARGE $	29. AMOUNT PAID $	30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.) SIGNED DATE	32. SERVICE FACILITY LOCATION INFORMATION a. b.	33. BILLING PROVIDER INFO & PH # (203) 555-6543 Dr. Jones 4231 Center Road Anytown, AS 01010 a. 123 456 7890 b.

NUCC Instruction Manual available at: www.nucc.org **PLEASE PRINT OR TYPE** APPROVED OMB-0938-1197 FORM 1500 (02-12)

YONDELIS® (trabectedin) ADMINISTRATION:

Hospital Outpatient Initiation of Prolonged Chemotherapy Infusion

Scenario: The drug infusion is started in the hospital outpatient setting using an external pump. The patient is then sent home for the remainder of the infusion and returns at the end of the infusion period.

Claim Form	Codes/Descriptors	Units/ Instructions	Medicare Claims	Non-Medicare Payer Claims
CMS 1450 (UB-04)	**G0498* –** Chemo extend IV infus w/pump	1 - Includes pump, supplies; do not bill additional codes	✓	verify with payer
	96416† – Initiation of prolonged chemotherapy infusion (more than 8 hours), requiring use of a portable or implantable pump	1 - Pump and supplies may be billed separately	N/A	verify with payer
	J9352 – Injection, trabectedin, 0.1 mg	0.1 mg = 1 unit Report dose in units	✓	✓

*G0498 is considered all-inclusive for the chemotherapy administration, the pump, supplies and follow-up visit at the conclusion of the infusion. Do not report additional codes or charges. Use of this code by non-Medicare payers may vary.

†96416 should not be reported on Medicare claims. Other payer requirements may vary.

Please consult with your local payer or contact Janssen CarePath at 877-CarePath (877-227-3728).

The following sample claim illustrates this scenario. ▶

YONDELIS® (trabectedin) ADMINISTRATION:

Hospital Outpatient Initiation of Prolonged Chemotherapy Infusion

Hospital Outpatient CMS-1450 (UB-04) Sample Claim Form

1. **Locator Box 42**—List revenue codes in ascending order.

2. **Locator Box 43**—Enter narrative description for corresponding revenue code (eg, IV therapy, clinic visit).

3. **Locator Box 44**—Indicate appropriate CPT and HCPCS codes and modifiers as required by the payer.

   YONDELIS®

   - J9352 - Injection, trabectedin, 0.1 mg

   Drug Administration

   - Medicare claims: G0498 (Chemo extend IV infus w/pump) is required. Do not bill additional codes for the pump or supplies
   - Non-Medicare claims: Payer requirements may vary

   Please consult with your local payer or contact Janssen CarePath at 877-CarePath (877-227-3728) to confirm payer requirements.

   Note: The PO modifier is required on institutional claims submitted by excepted, off-campus, provider-based departments; the PN modifier is required on institutional claims submitted by non-excepted, off-campus, provider-based departments. Neither the PO nor the PN modifier is to be reported for a provider-based department that is "on campus".[8]

   Note: HCPCS modifiers must be reported for all 340B acquired drugs. Providers that are not excepted from the 340B payment policy will report modifier JG. Providers that are excepted from the 340B payment policy will report modifier TB.[9]

4. **Locator Box 46**—Enter the amount of drug in HCPCS units:

   - J9352 – Bill 1 unit for every 0.1 mg of YONDELIS® (10 units contained in each 1-mg vial)

5. **Locator Box 47**—Indicate total charges.

6. **Locator Box 67**—Indicate diagnosis using appropriate ICD-10-CM codes. Use diagnosis codes to the highest level of specificity for the date of service and enter the diagnoses in priority order. For ICD-10 diagnoses enter "0" in Locator Box 66.

Please read Important Safety Information on pages 24-25.
Click here to read the full Prescribing Information for Yondelis®.

YONDELIS® (trabectedin) ADMINISTRATION:

Hospital Outpatient Initiation of Prolonged Chemotherapy Infusion

Hospital Outpatient CMS-1450 Sample Claim Form

1 Anytown Hospital 160 Main Street Anytown, Anystate 01010	2 Pay-to-name Pay-to-address Pay-to-city/state	3a PAT. CNTL # XX-XXXX b. MED. REC. # DOE 1234-97	4 TYPE OF BILL
		5 FED. TAX NO. 010001010	6 STATEMENT COVERS PERIOD FROM THROUGH

8 PATIENT NAME a John B. Doe (ID) b John B. Doe	9 PATIENT ADDRESS a 3914 Spruce St. b Anytown,	c AS	d 01010	e US	10 BIRTHDATE 07-01-45	11 SEX M	ADMISSION 12 DATE 13 HR 14 TYPE 15 SRC

16 DHR | 17 STAT | CONDITION CODES 18 19 20 21 22 23 24 25 26 27 28 | 29 ACDT STATE | 30

31 OCCURRENCE CODE DATE	32 OCCURRENCE CODE DATE	33 OCCURRENCE CODE DATE	34 OCCURRENCE CODE DATE	35 OCCURRENCE SPAN CODE FROM THROUGH	36 OCCURRENCE SPAN CODE FROM THROUGH	37
a						a
b						b

38

39 VALUE CODES CODE AMOUNT	40 VALUE CODES CODE AMOUNT	41 VALUE CODES CODE AMOUNT
a		
b		
c		
d		

1 2 3

	42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
1								1
2								2
3								3
4	0260	IV therapy	G0498	01-01-18	1			4
5								5
6								6
7								7
8	0636	YONDELIS® (trabectedin)	J9352	01-01-18	30			8
9								9
10								10
11								11
12								12
13								13
14					4	5		14
15								15
16								16
17								17
18								18
19								19
20								20
21								21
22								22
23		PAGE ____ OF ____	CREATION DATE		TOTALS			23

50 PAYER NAME	51 HEALTH PLAN ID	52 REL. INFO	53 ASG. BEN.	54 PRIOR PAYMENTS	55 EST. AMOUNT DUE	56 NPI	57
A Medicare						246 890 1234	OTHER PRV ID
B							
C							

58 INSURED'S NAME	59 P REL	60 INSURED'S UNIQUE ID	61 GROUP NAME	62 INSURANCE GROUP NO.
A				
B				
C				

63 TREATMENT AUTHORIZATION CODES	64 DOCUMENT CONTROL NUMBER	65 EMPLOYER NAME
A		
B		
C		

6

66 DX	A	B	C	D	E	F	G	H	68
C49.9									
0	I	J	K	L	M	N	O	P	Q	

69 ADMIT DX	70 PATIENT REASON DX	a	b	c	71 PPS CODE	72 ECI	a	b	c	73

74 PRINCIPAL PROCEDURE CODE DATE	a. OTHER PROCEDURE CODE DATE	b. OTHER PROCEDURE CODE DATE	75
c. OTHER PROCEDURE CODE DATE	d. OTHER PROCEDURE CODE DATE	e. OTHER PROCEDURE CODE DATE	

76 ATTENDING	NPI 123 456 7890	QUAL	
LAST Jones	FIRST John		
77 OPERATING	NPI	QUAL	
LAST	FIRST		
78 OTHER	NPI	QUAL	
LAST	FIRST		
79 OTHER	NPI	QUAL	
LAST	FIRST		

80 REMARKS	81CC		
	a		
	b		
	c		
	d		

UB-04 CMS-1450 APPROVED OMB NO. 0938-0997 NUBC National Uniform Billing Committee THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF.

YONDELIS® (trabectedin) ADMINISTRATION:

Hospital Outpatient Administration of Chemotherapy Infusion

Scenario: If there is medical necessity for a patient to receive their infusion under continuous monitoring, and a hospital outpatient facility has the capability of providing such services, this coding scenario may be applicable. The patient remains in a hospital setting designated as "outpatient" for the entire 24-hour infusion and is classified as a hospital outpatient throughout the entire procedure.

Please note: Medicare does not permit observation services to be billed concurrently with diagnostic or therapeutic services for which active monitoring is a part of the procedure (eg, colonoscopy, chemotherapy).[10]

Claim Form	Codes/Descriptors	Units/ Instructions	Medicare Claims	Non-Medicare Payer Claims
CMS 1450 (UB-04)	**96413 –** Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug	1	✓	✓
	96415 – Each additional hour (List separately in addition to code for primary procedure)	23	✓	✓
	J9352 – Injection, trabectedin, 0.1 mg	0.1 mg = 1 unit Report dose in units	✓	✓

Please consult with your local payer or contact Janssen CarePath at 877-CarePath (877-227-3728).

The following sample claim illustrates this scenario. ▶

YONDELIS® (trabectedin) ADMINISTRATION:

Hospital Outpatient Administration of Chemotherapy Infusion

Hospital Outpatient Sample Claim Form: CMS-1450 (UB-04)

1. **Locator Box 42**—List revenue codes in ascending order.

2. **Locator Box 43**—Enter narrative description for corresponding revenue code (eg, IV therapy, clinic visit).

3. **Locator Box 44**—Indicate appropriate CPT and HCPCS codes and modifiers as required by the payer.

   YONDELIS®

   - J9352 - Injection, trabectedin, 0.1 mg

   Drug Administration

   - CPT code 96413 - Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
   - CPT code 96415 - Each additional hour (list separately in addition to code for primary procedure)

   Payer policies may vary. Please consult with your local payer or contact Janssen CarePath at 877-CarePath (877-227-3728) to confirm payer requirements.

   Note: The PO modifier is required on institutional claims submitted by excepted, off-campus, provider-based departments; the PN modifier is required on institutional claims submitted by non-excepted, off-campus, provider-based departments. Neither the PO nor the PN modifier is to be reported for a provider-based department that is "on campus".[8]

   Note: HCPCS modifiers must be reported for all 340B acquired drugs. Providers that are not excepted from the 340B payment policy will report modifier JG. Providers that are excepted from the 340B payment policy will report modifier TB.[9]

4. **Locator Box 46**—Enter the amount of drug in HCPCS units:

   - J9352 – Bill 1 unit for every 0.1 mg of YONDELIS® (10 units contained in each 1-mg vial)

5. **Locator Box 47**—Indicate total charges.

6. **Locator Box 67**—Indicate diagnosis using appropriate ICD-10-CM codes. Use diagnosis codes to the highest level of specificity for the date of service and enter the diagnoses in priority order. For ICD-10 diagnoses enter "0" in Locator Box 66.

YONDELIS® (trabectedin) ADMINISTRATION:

Hospital Outpatient Administration of Chemotherapy Infusion

Hospital Outpatient CMS-1450 Sample Claim Form: HOPD Infusion

1 Anytown Hospital 160 Main Street Anytown, Anystate 01010	2 Pay-to-name Pay-to-address Pay-to-city/state	3a PAT. CNTL # XX-XXXX b. MED. REC. # DOE 1234-97	4 TYPE OF BILL
		5 FED. TAX NO. 010001010	6 STATEMENT COVERS PERIOD FROM THROUGH
8 PATIENT NAME a John B. Doe (ID) b John B. Doe	9 PATIENT ADDRESS a 3914 Spruce St. b Anytown, c AS d 01010 e US		
10 BIRTHDATE 07-01-45	11 SEX M	12 ADMISSION DATE 13 HR 14 TYPE 15 SRC	16 DHR
17 STAT	18 19 20 21 22 23 24 25 26 27 28 CONDITION CODES	29 ACDT STATE	30

31 OCCURRENCE CODE DATE	32 OCCURRENCE CODE DATE	33 OCCURRENCE CODE DATE	34 OCCURRENCE CODE DATE	35 OCCURRENCE SPAN CODE FROM THROUGH	36 OCCURRENCE SPAN CODE FROM THROUGH	37
a						a
b						b

38	39 VALUE CODES CODE AMOUNT	40 VALUE CODES CODE AMOUNT	41 VALUE CODES CODE AMOUNT
	a		
	b		
	c		
	d		

1 2 3

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
0260	IV therapy	96413	01-01-18	1			
0260	IV therapy	96415	01-01-18	23			
0636	YONDELIS® (trabectedin)	J9352	01-01-18	30			
	PAGE ____ OF ____	CREATION DATE		TOTALS			

4 5

50 PAYER NAME	51 HEALTH PLAN ID	52 REL. INFO	53 ASG. BEN.	54 PRIOR PAYMENTS	55 EST. AMOUNT DUE	56 NPI	57
A Medicare						246 890 1234	
B						OTHER PRV ID	
C							

58 INSURED'S NAME	59 P REL	60 INSURED'S UNIQUE ID	61 GROUP NAME	62 INSURANCE GROUP NO.
A				
B				
C				

63 TREATMENT AUTHORIZATION CODES	64 DOCUMENT CONTROL NUMBER	65 EMPLOYER NAME
A		
B		
C		

6

66 DX	A	B	C	D	E	F	G	H	68
0	C49.9								
	I J	K	L	M	N	O	P	Q	

69 ADMIT DX	70 PATIENT REASON DX a b c	71 PPS CODE	72 ECI a b c	73

74 PRINCIPAL PROCEDURE CODE DATE	a. OTHER PROCEDURE CODE DATE	b. OTHER PROCEDURE CODE DATE	75
c. OTHER PROCEDURE CODE DATE	d. OTHER PROCEDURE CODE DATE	e. OTHER PROCEDURE CODE DATE	

80 REMARKS	81CC a		
	b		
	c		
	d		

76 ATTENDING	NPI 123 456 7890	QUAL	
LAST Jones	FIRST John		
77 OPERATING	NPI	QUAL	
LAST	FIRST		
78 OTHER	NPI	QUAL	
LAST	FIRST		
79 OTHER	NPI	QUAL	
LAST	FIRST		

UB-04 CMS-1450 APPROVED OMB NO. 0938-0997 NUBC National Uniform Billing Committee THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS — YONDELIS® (trabectedin) is contraindicated in patients with known severe hypersensitivity, including anaphylaxis, to trabectedin.

WARNINGS AND PRECAUTIONS

Neutropenic sepsis, including fatal cases, can occur. In Trial ET743-SAR-3007, the incidence of Grade 3 or 4 neutropenia, based on laboratory values, was 43% (161/378). Median time to the first occurrence of Grade 3 or 4 neutropenia was 16 days (range: 8 days to 9.7 months). Median time to complete resolution of neutropenia was 13 days (range: 3 days to 2.3 months). Febrile neutropenia (fever ≥38.5°C with Grade 3 or 4 neutropenia) occurred in 18 patients (5%) treated with YONDELIS®. Ten patients (2.6%) experienced neutropenic sepsis, 5 of whom had febrile neutropenia, which was fatal in 4 patients (1.1%). Assess neutrophil count prior to administration of each dose of YONDELIS® and periodically throughout the treatment cycle. Withhold or reduce dose of YONDELIS® based on severity of adverse reaction.

Rhabdomyolysis — YONDELIS® can cause rhabdomyolysis and musculoskeletal toxicity. In Trial ET743-SAR-3007, rhabdomyolysis leading to death occurred in 3 (0.8%) of the 378 patients receiving YONDELIS®. Elevations in creatine phosphokinase (CPK) occurred in 122 (32%) of the 378 patients receiving YONDELIS®, including Grade 3 or 4 CPK elevation in 24 patients (6%), compared to 15 (9%) of the 172 patients receiving dacarbazine with any CPK elevation, including 1 patient (0.6%) with Grade 3 CPK elevation. Among the 24 patients receiving YONDELIS® with Grade 3 or 4 CPK elevation, renal failure occurred in 11 patients (2.9%); rhabdomyolysis with the complication of renal failure occurred in 4 of these 11 patients (1.1%). Median time to first occurrence of Grade 3 or 4 CPK elevations was 2 months (range: 1 to 11.5 months). Median time to complete resolution was 14 days (range: 5 days to 1 month). Assess CPK levels prior to each administration of YONDELIS®. Withhold, reduce dose, or permanently discontinue based on severity of adverse reaction.

Hepatotoxicity, including hepatic failure, can occur. Patients with serum bilirubin levels above the upper limit of normal or AST or ALT levels >2.5 x upper limit of normal were not enrolled in Trial ET743-SAR-3007. In Trial ET743-SAR-3007, the incidence of Grade 3-4 elevated liver function tests (defined as elevations in ALT, AST, total bilirubin, or alkaline phosphatase) was 35% (134/378) in patients receiving YONDELIS®. Median time to development of Grade 3-4 elevation in ALT or AST was 29 days (range: 3 days to 11.5 months). Of the 134 patients with Grade 3 to 4 elevations in LFTs, 114 (85%) experienced complete resolution with the median time to complete resolution of 13 days (range: 4 days to 4.4 months). In Trial ET743-SAR-3007, the incidence of drug-induced liver injury (defined as concurrent elevation in ALT or AST of more than three times the upper limit of normal, alkaline phosphatase less than two times the upper limit of normal, and total bilirubin at least two times the upper limit of normal) was 1.3% (5/378) in patients receiving YONDELIS®. ALT or AST elevation greater than eight times the upper limit of normal occurred in 18% (67/378) of patients receiving YONDELIS®. Assess LFTs prior to each administration of YONDELIS® and as clinically indicated based on underlying severity of pre-existing hepatic impairment. Manage elevated LFTs with treatment interruption, dose reduction, or permanent discontinuation based on severity and duration of LFT abnormality.

Important Safety Information continued on next page.

Click here to read the full Prescribing Information for Yondelis®.

IMPORTANT SAFETY INFORMATION (continued from previous page)

WARNINGS AND PRECAUTIONS (continued)

Cardiomyopathy, including cardiac failure, congestive heart failure, ejection fraction decreased, diastolic dysfunction, or right ventricular dysfunction can occur. In Trial ET743-SAR-3007, a significant decrease in left ventricular ejection fraction (LVEF) was defined as an absolute decrease of ≥15% or below the lower limit of normal with an absolute decrease of ≥5%. Patients with a history of New York Heart Association Class II to IV heart failure or abnormal LVEF at baseline were ineligible. In Trial ET743-SAR-3007, cardiomyopathy occurred in 23 patients (6%) receiving YONDELIS® (trabectedin) and in four patients (2.3%) receiving dacarbazine. Grade 3 or 4 cardiomyopathy occurred in 15 patients (4%) receiving YONDELIS® and 2 patients (1.2%) receiving dacarbazine; cardiomyopathy leading to death occurred in 1 patient (0.3%) receiving YONDELIS® and in none of the patients receiving dacarbazine. The median time to development of Grade 3 or 4 cardiomyopathy in patients receiving YONDELIS® was 5.3 months (range: 26 days to 15.3 months). Patients with LVEF < lower limit of normal, prior cumulative anthracycline dose of ≥300 mg/m^2, age ≥65 years, or a history of cardiovascular disease may be at increased risk of cardiac dysfunction. Assess LVEF by echocardiogram (ECHO) or multigated acquisition (MUGA) scan before initiation of YONDELIS® and at 2- to 3-month intervals thereafter until YONDELIS® is discontinued. Discontinue treatment with YONDELIS® based on severity of adverse reaction.

Capillary leak syndrome (CLS) characterized by hypotension, edema, and hypoalbuminemia has been reported with YONDELIS®, including serious CLS resulting in death. Monitor for signs and symptoms of CLS. Discontinue YONDELIS® and promptly initiate standard management for patients with CLS, which may include a need for intensive care.

Extravasation Resulting in Tissue Necrosis — Extravasation of YONDELIS®, resulting in tissue necrosis requiring debridement, can occur. Evidence of tissue necrosis can occur more than 1 week after the extravasation. There is no specific antidote for extravasation of YONDELIS®. Administer YONDELIS® through a central venous line.

Embryo-Fetal Toxicity — Based on its mechanism of action, YONDELIS® can cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during therapy and for at least 2 months after the last dose of YONDELIS®. Advise males with female partners of reproductive potential to use effective contraception during therapy and for at least 5 months after the last dose of YONDELIS®.

Adverse Reactions — The most common (≥20%) adverse reactions are nausea (75%), fatigue (69%), vomiting (46%), constipation (37%), decreased appetite (37%), diarrhea (35%), peripheral edema (28%), dyspnea (25%), and headache (25%).

The most common (≥5%) grades 3-4 laboratory abnormalities are: neutropenia (43%), increased ALT (31%), thrombocytopenia (21%), anemia (19%), increased AST (17%), and increased creatine phosphokinase (6.4%).

DRUG INTERACTIONS

Effect of Cytochrome CYP3A Inhibitors — Avoid using strong CYP3A inhibitors (e.g., oral ketoconazole, itraconazole, posaconazole, voriconazole, clarithromycin, telithromycin, indinavir, lopinavir, ritonavir, boceprevir, nelfinavir, saquinavir, telaprevir, nefazodone, conivaptan) in patients taking YONDELIS®. If a strong CYP3A inhibitor for short-term use (i.e., less than 14 days) must be used, administer the strong CYP3A inhibitor 1 week after the YONDELIS® infusion, and discontinue it the day prior to the next YONDELIS® infusion.

Effect of Cytochrome CYP3A Inducers — Avoid using strong CYP3A inducers (e.g., rifampin, phenobarbital, St. John's wort) in patients taking YONDELIS®.

cp-63569v2

Click here to read the full Prescribing Information for Yondelis®.

Yondelis® (trabectedin)

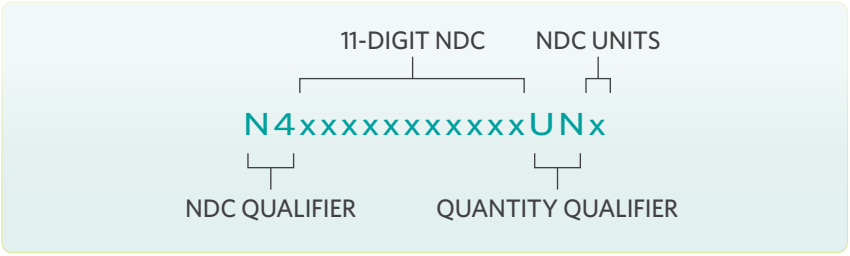
APPENDIX A: ADDITIONAL CODING INFORMATION

Billing With National Drug Codes (NDCs)[11]

Reporting NDCs is required for Medicaid and Medicare/Medicaid crossover claims to support the Medicaid drug rebate process. NDCs may also be reported to facilitate claims processing and may be required by payers. Accurate NDC reporting must include specific elements:

- NDC (11-digit format)
- NDC qualifier: N4
- NDC unit of measure qualifier (eg, UN, ML, GR, etc)
- NDC units

NDC billing information must conform to the HIPAA 5010 standard, thus follow a specific format:



The corresponding entry for one vial of YONDELIS® (trabectedin) is: N459676061001UN1. The number of NDC units to be billed is based on the dose.

Example: NDC Unit Calculation

AMOUNT TO BE BILLED: 3 mg YONDELIS®	
HCPCS Code	J9352
HCPCS Code description	Injection, trabectedin, 0.1 mg
Number of HCPCS units	30
NDC (11-digit billing format)	59676-0610-01
NDC description	Single-use vial containing 1 mg of trabectedin lyophilized powder
NDC unit of measure	UN
NDC units	3

APPENDIX A: ADDITIONAL CODING INFORMATION (cont'd)

Billing With National Drug Codes (NDCs) (cont'd)

To calculate the NDC units:

- The amount to be billed is 3 mg
- The NDC unit of measure is UN (powder for reconstitution)
- Mg must be converted to UN
- The NDC description is 1-mg vial
- Divide the amount to be billed (3 mg) by the number in the NDC description (3/1 = 3)

The corresponding CMS-1500 form entry for a 3-mg dose of YONDELIS®[12]:

	24. A. DATE(S) OF SERVICE From MM	DD	YY	To MM	DD	YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1	N459676061001UN3															
	01	02	17	01	02	17			J9352		A	xxxx	30		NPI	
2															NPI	
3															NPI	
4															NPI	

I OR SUPPLIER INFORMATION

The corresponding CMS-1450 form entry for a 3-mg dose of YONDELIS®[13]:

	42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS
1		N459676061001UN3			3
2					
3					

Place of Service Codes[14]

The Place of Service (POS) code set provides setting information necessary to appropriately pay Medicare and Medicaid claims. The place of service is the location of the provider's face-to-face encounter with the beneficiary. POS codes are required on all claims for professional services (billed on CMS-1500). Under the Physician Fee Schedule (PFS), some procedures have separate rates for physician services when provided in facility and non-facility setting, therefore it is important to accurately designate the POS in order to assure appropriate payment. The physician practice location is considered "non-facility" (NF), allowing for the practice expenses to be included in the payment for professional services under the Physician Fee Schedule (PFS). When professional services are performed in a facility (eg, hospital outpatient department) the practice does not incur the same expense (overhead, staff, equipment and supplies, etc), thus payment under the PFS is generally lower for facility-based services than nonfacility.

APPENDIX A: ADDITIONAL CODING INFORMATION (cont'd)

Place of Service Codes (cont'd)

The physician practice setting is indicated with POS code 11. In order to differentiate between on-campus and off-campus provider-based departments CMS created a new POS code (POS 19) and revised the POS code description for hospital outpatient (POS 22):

POS Code	POS Location	POS Descriptor
11	Office	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.
19	Off-Campus – Hospital Outpatient	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. (Effective January 1, 2016)
22	On-Campus – Hospital Outpatient	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. (Description change effective January 1, 2016)

When billing professional services on the CMS-1500, enter the appropriate POS code in Item 24B, adjacent to each HCPCS code.

Modifiers[7]

Code modifiers provide a means to report or indicate that a service or procedure has been altered by some specific circumstance but not changed in its definition or code. They add more information and help to eliminate the appearance of duplicate billing and unbundling. Appropriately used, modifiers increase coding and reimbursement accuracy. The following table summarizes modifiers that may be applicable to coding and billing YONDELIS® (trabectedin) in physician offices and hospital outpatient departments.

APPENDIX A: ADDITIONAL CODING INFORMATION
(cont'd)

CPT and HCPCS Modifiers

Modifier	Description	Indication and Placement	CMS-1500 Item 24D	CMS-1450 Locator Box 44
25	Significant, separately identifiable evaluation and management service by the same physician on the same day of the procedure or other service[7]	• Patient requires distinct E/M service in addition to the infusion procedure[7] • Must be substantiated with relevant documentation[7] • Append the modifier to the relevant E/M code[7]	✓	✓
JW	Drug amount discarded/not administered to any patient[4]	• Unused drug remains after applicable dose is administered from single-use vial[15] • Append the modifier to the drug code on a line separate from that reporting the administered dose[15]	✓	✓
PO*	Excepted services provided at an off-campus, outpatient provider-based department of a hospital[4]	• To be reported on each claim line for excepted services furnished in an off-campus, provider-based department of a hospital and billed on an institutional claim[8]	N/A	✓ Required by Medicare
PN*	Non-excepted service provided at an off-campus, outpatient, provider-based department of a hospital[4]	• To be reported on each claim line for nonexcepted services furnished in an off-campus provider-based department of a hospital and billed on an institutional claim[8]	N/A	✓ Required by Medicare
JG	Drug or biological acquired with 340B Drug Pricing Program Discount[9]	• Beginning January 1, 2018, must be reported by providers that are NOT excepted† from the 340B payment policy[9] • To be reported on the same claim line as the drug HCPCS code for all 340B acquired drugs[9]	N/A	✓ Required by Medicare
TB	Drug or biological acquired with 340B Drug Pricing Program Discount, reported for informational purposes[9]	• Beginning January 1, 2018, must be reported by providers that ARE excepted† from the 340B payment policy[9] • To be reported on the same claim line as the drug HCPCS code for all 340B acquired drugs[9]	N/A	✓ Required by Medicare

*Neither the PO nor the PN modifier is to be reported for dedicated emergency departments, remote locations or satellite facilities of a hospital, or a provider-based department that is "on campus".[8]

†This policy does not apply to critical access hospitals (CAHs) or Maryland hospitals; for 2018, the following provider types are excepted from the 340B payment policy: rural sole community hospitals, children's hospitals, PPS-exempt cancer hospitals and non-excepted, off-campus, provider-based departments.[9]

Please read Important Safety Information on pages 24-25.

Click here to read the full Prescribing Information for Yondelis®.

APPENDIX B: COMMUNICATING WITH YOUR PAYER

- Pre-Billing Checklist
- Medicare Administrative Contractors (MACs)

PRE-BILLING CHECKLIST

To improve billing accuracy and efficiency, it may be helpful to perform a pre-billing review prior to submitting any claim to a payer. The following may be considered:

Coverage

- ❑ Insurance has been verified
- ❑ This is a covered service
- ❑ If applicable, the authorization was obtained
- ❑ Specific payer requirements were followed

Coding

- ❑ All of the required information is included on the claim
- ❑ The correct codes (ICD-10, NDC, CPT, HCPCS, etc) were reported
- ❑ The billed units are accurate and consistent with the J code descriptor
- ❑ If NDC billing is required, the quantity and units of measurement are accurate
- ❑ Any required, payer-specific modifiers have been properly applied
- ❑ If a separate and distinct E/M service is reported it is identified with modifier-25

Documentation

- ❑ Medical necessity is documented
- ❑ Documentation supports payer requirements
- ❑ Any discarded drug is appropriately recorded in the medical record
- ❑ Drug administration services are accurately recorded:
  - Method of administration (infusion, injection, IV push, etc)
  - Vascular access type/location used for each service
  - Time of drug administration, including start/stop times for infusions

SPECIALTY DISTRIBUTORS

The following specialty distributors are authorized to sell YONDELIS® (trabectedin) and are able to service institutions and/or physician offices and community oncology practices. This represents a partial list of specialty distributors supplying YONDELIS®. It is not intended to serve as a comprehensive list. These specialty distributors were selected for the YONDELIS® network due to their geographic coverage, payer coverage, oncology, clinical, operational, and supportive services. Janssen Products, LP, does not endorse the use of any of the listed distributors in particular.

Specialty Distributor	Contact Service Phone	Fax	Website
ASD Healthcare	1-800-746-6273	1-800-547-9413	https://www.asdhealthcare.com
Cardinal Health Specialty Pharmaceutical Distribution	**Physician Offices:** 1-877-453-3972 **Hospitals/All Other:** 1-866-677-4844	1-614-652-7043	http://www.cardinalhealth.com/en/services/acute/logistics-solutions-acute/distribution/specialty-distribution.html
McKesson Plasma & Biologics	1-877-625-2566	1-888-752-7626	https://www.mckesson.com Email: plasma@mckesson.com
McKesson Specialty Health	**Multispecialty:** 1-855-477-9800 **Oncology:** 1-800-482-6700	**Multispecialty:** 1-800-800-5673 **Oncology:** 1-800-289-9285	http://www.mckessonspecialtyhealth.com
Oncology Supply	1-800-633-7555	1-800-248-8205	https://www.oncologysupply.com

Yondelis® (trabectedin)

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If you have any questions or need additional information, please call 877-CarePath (877-227-3728) or visit www.YONDELIS.com.

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Please read Important Safety Information on pages 24-25 and **click here to read the full Prescribing Information for Yondelis®.**