Dilapan-S®
CERVICAL DILATOR

REIMBURSEMENT GUIDE

The following provides 2023 Medicare Physician Fee Schedule (MPFS) and facility national payment rates for the CPT® code(s) that may be reported for the induction of labor procedure. Payers may have specific coding, reimbursement requirements and policies. Prior to filing claims, it is recommended that healthcare professionals verify current reimbursement and policies with their local payer. **Payment will vary by region.**

Device Description

Dilapan-S® is an FDA-cleared, osmotic, hygroscopic, cervical dilator rod composed of Aquacryl®, a synthetic patented hydrogel. Each Dilapan-S rod absorbs fluid from the surrounding cervical tissue and expands to several times its original diameter, gradually softening and dilating the cervix.[1,2] Dilapan-S contains no pharmacologically active substance.[1]

Indications for Use

Dilapan-S® is for use by healthcare professionals trained in OB/GYN whenever cervical softening and dilation are desired, such as for cervical ripening during term labor induction or gynecological procedures that require cervical preparation.[1]

Physician Reimbursement

Medicare reimburses physicians according to the Medicare Physician Fee Schedule (MPFS), which is based on Relative Value Units (RVUs), and payments vary by geographic region. Physicians bill Medicare and other payers for services performed regardless of whether the service takes place in the physician's office, a hospital, or an outpatient facility.

CY 2023 Physician Payment

CPT® Code[3]	Description	Non-Facility (In-Office)		Facility (Inpatient; Outpatient)	
		RVUs	Medicare National Payment[4]	RVUs	Medicare National Payment[4]
59200	Insertion of cervical dilator (e.g., laminaria, prostaglandin) (separate procedure)	3.19	$105.51	1.32	$43.64

Modifier

- If this service was performed one day or more prior to a delivery, it can be reported separately. Use modifier 59 or other appropriate X{EPSU} sub-modifier per payer policy.[5]
- Modifier 59: Distinct Procedural Service[3]
- If this service was performed on the same day as a delivery, it is considered part of the global obstetric package and not reported separately.[5]

Physician In-Office

Billing CMS-1500-Form[5] Identifying Dilapan-S®

1. **Box 19 – Additional Claim Information:** Allows for "text" to include more information about the claim to the payer (e.g., identify Dilapan-S for cervical ripening).

2. **Box 21 – Diagnosis or Nature of Illness or Injury:** Apply appropriate diagnosis codes as required for reimbursement of CPT 59200.

   Examples used but not limited to: N88.2 – Stricture and stenosis of cervix uteri; Z3A.40 – 40 Weeks gestation of pregnancy; O13.9 – Gestational hypertension.

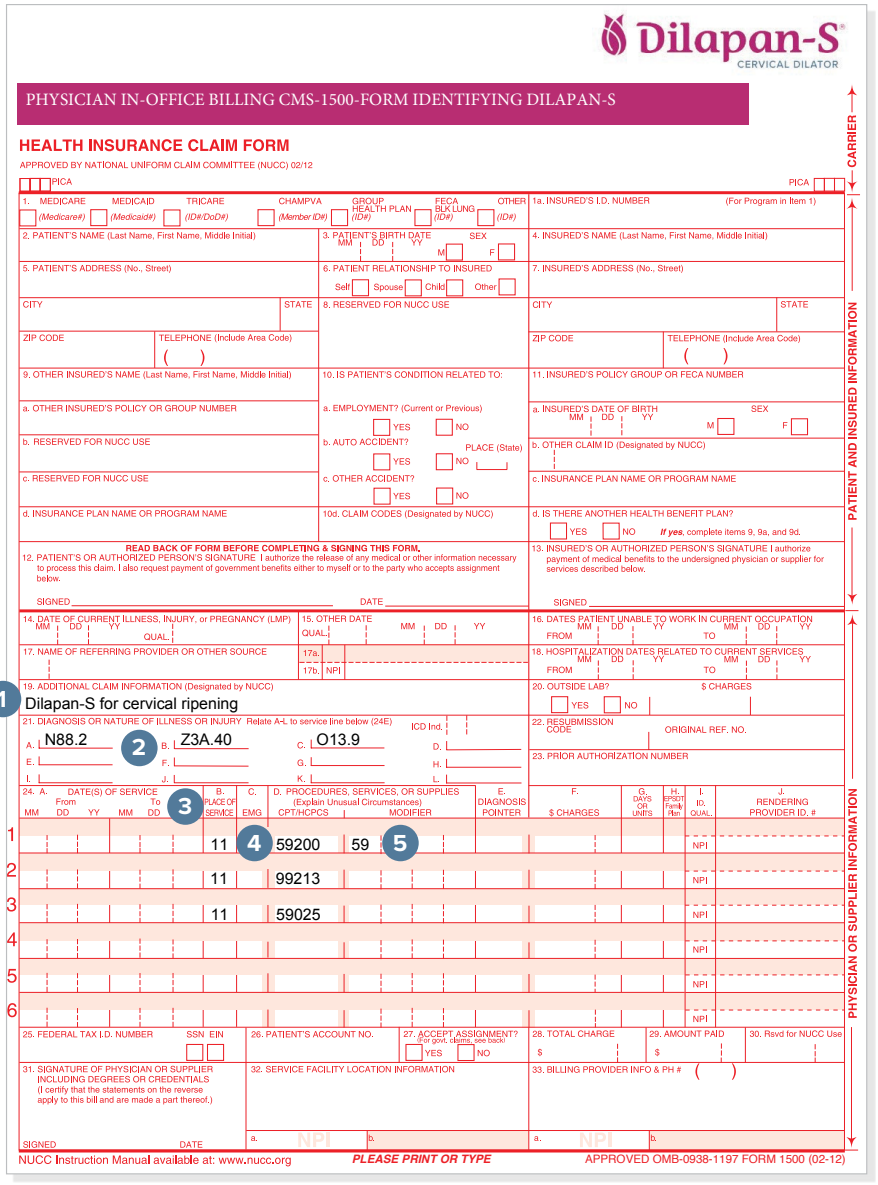
3. **Box 24 B. – Place of Service**: 11 Office

4. **Box 24 D. Procedures, Services, or Supplies – CPT/HCPCS:** Bill for the insertion of a cervical dilator using CPT code 59200 – Insertion of cervical dilator (e.g., laminaria, prostaglandin) (separate procedure. *Note: There is no CPT code and no separate payment for removal of Dilapan-S.*)

   Additional Examples used for CPT/HCPCS: CPT Code 99213 – Evaluation and management (E&M) of an established patient, 20-30 minutes of total time spent on the date of encounter; CPT Code 59025 – Fetal non-stress test.

5. **Box 24 D. Procedures, Services, or Supplies – Modifier:** When insertion of cervical dilator is performed one or more days prior to a delivery, append Modifier 59 to describe the insertion as a Distinct & Separate Procedure.

Payers may require Medical documentation (e.g., medical dictation notes) supporting medical necessity for CPT 59200.



Dilapan-S® CERVICAL DILATOR

PHYSICIAN IN-OFFICE BILLING CMS-1500-FORM IDENTIFYING DILAPAN-S

HEALTH INSURANCE CLAIM FORM

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

PICA

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

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE MM DD YY SEX M F

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED Self Spouse Child Other

7. INSURED'S ADDRESS (No., Street)

CITY STATE

8. RESERVED FOR NUCC USE

CITY STATE

ZIP CODE TELEPHONE (Include Area Code) ( )

ZIP CODE TELEPHONE (Include Area Code) ( )

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

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

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

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC) — 1 Dilapan-S for cervical ripening

20. OUTSIDE LAB? YES NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.

A. N88.2 2 B. Z3A.40 C. O13.9 D.

E. F. 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	3 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		11	4	59200	59 5					NPI	
2		11		99213						NPI	
3		11		59025						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. NPI b.

33. BILLING PROVIDER INFO & PH # ( )

a. NPI b.

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

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

If insertion occurs more than 24 hours prior to delivery, with appropriate modifier and documentation of medical necessity, CPT 59200 is reported separately (outside the Maternity Global Bundle).

For illustrative purposed only. Example of billing claim form does not contain an exhaustive list of services which may be offered to a patient during the insertion service encounter. Place of service code depends on the site of care where procedure is performed. Diagnosis codes are based on the patient's condition. Use modifier 59 or X{EPSU} subset per patient policy. The physician is responsible for appropriate selection of procedure/service/treatment CPT/HCPCS codes.

Outpatient Facility Reimbursement

Hospital outpatient services are reimbursed under the Medicare Outpatient Prospective Payment System (OPPS) based on the associated Ambulatory Payment Classification (APC). Procedures requiring similar resources are grouped into APCs and facilities are paid a lump sum payment for the services provided.

CY 2023 Hospital Outpatient Payment

CPT® Code[3]	Description	Hospital Outpatient		
		APC	Status Indicator[6]	Medicare National Payment[7]
59200	Insertion of cervical dilator (e.g., laminaria, prostaglandin) (separate procedure)	5412	T	$291.96
G0463	Hospital outpatient clinic visit	5012	J2	$120.86

Status Indicator
Each CPT code in the OPPS is assigned a status indicator to signify whether a discount (payment reduction) applies to the respective APC payment. The following status indicators are represented in this procedure:

- "T" Procedure or service, multiple procedure reduction applies. Paid under OPPS; separate APC payment.
- "J2" Hospital Part B services that may be paid through a Comprehensive APC. Paid under OPPS; Addendum B displays APC assignments when services are separately payable.

Revenue Code[8]
Generally, CMS does not instruct hospitals on the assignment of HCPCS codes to revenue codes for services provided under OPPS since hospital assignment of cost vary. Where explicit instructions are not provided, hospitals are to report charges under the revenue code that will result in the charges being assigned to the same cost center to which the cost of those services are assigned in the cost report.
Note: The "X" below serves as a placeholder for the fourth numerical digit (possible range 0-9), please consider the appropriate digit assignment.

Examples used but not limited to:

- 027X – Medical/Surgical Supplies and Devices (Also see 062X, an extension of 027X): Code indicates charges for supply items required for patient care. Rationale: Additional breakdowns are provided for items that hospitals may wish to identify because of internal or third-party payer requirements.
- 036X – Operating Room Services: Charges for services provided to patients by specially trained nursing personnel who provide assistance to physicians in the performance of surgical and related procedures during and immediately following surgery as well the operating room (heat, lights) and equipment. Rationale: Permits identification of particular services.
- 050X – Outpatient Services: Outpatient charges for services rendered to an outpatient who is admitted as an inpatient before midnight of the day following the date of service. This revenue code is no longer used for Medicare.
- 072X – Labor Room/Delivery: Charges for labor and delivery room services provided by specially trained nursing personnel to patients, including prenatal care during labor, assistance during delivery, postnatal care in the recovery room, and minor gynecologic procedures if they are performed in the delivery suite.

Inpatient Facility Reimbursement

ICD-10-PCS (Procedure Classification System) for Inpatient Procedure

ICD-10-PCS is used for inpatient hospital settings in the United States. ICD-10-PCS is the official system of assigning codes to procedures associated with hospital utilization. These codes support data collection, payment, and electronic health records. ICD-10-PCS is intended for use by healthcare professionals, health care organizations, and insurance programs.

ICD-10-PCS[9]	Description
0U7C7ZZ	Dilation of Cervix, Via Natural or Artificial Opening

Medicare Severity-Diagnosis Related Groups (MS-DRGs)

Hospital payments for inpatient services or procedures are usually based on Medicare Severity Diagnosis Related Group (MS-DRGs aka DRGs), case rates, per diem rates, or a line-item payment methodology. Medicare assigns a hospital inpatient stay to a DRG based on the reported diagnoses, condition of the patient, and reason for the procedure. Hospitals generally receive a fixed, predetermined payment for each DRG, which includes all costs associated with the patient's hospital stay.

FY 2023 Final Hospital Inpatient Potential MS-DRG Assignment

MS-DRG	Description	Relative Weight	Medicare National Payment[10]
783	C-section with sterilization w/MCC	1.9297	$12,787.06
784	C-section with sterilization w/CC	1.0440	$7,140.06
785	C-section with sterilization w/o CC/MCC	0.9121	$6,299.10
786	C-section without sterilization w/MCC	1.6150	$10,780.61
787	C-section without sterilization w/CC	1.0653	$7,275.87
788	C-section without sterilization w/o CC/MCC	0.8724	$6,045.99
796	Vaginal delivery with sterilization/D&C w/MCC	1.3130	$8,855.14
797	Vaginal delivery with sterilization/D&C w/CC	0.9279	$6,399.84
798	Vaginal delivery with sterilization/D&C w/o CC/MCC	0.9279	$6,399.84
805	Vaginal delivery w/o sterilization/D&C w/MCC	1.0056	$6,895.23
806	Vaginal delivery w/o sterilization/D&C w/CC	0.6978	$4,932.78
807	Vaginal delivery w/o sterilization/D&C w/o CC/MCC	0.6314	$4,509.43

CC – Complications or Comorbidities; MCC – Major Complications or Comorbidities

Facility

Billing CMS-1450-Form[11] Identifying Dilapan-S®

1. **Field 42 – Revenue Code.** Hospitals are to report charges under the revenue code that will result in the charges being assigned to the same cost center to which the costs of those services are assigned in the cost report.

   For example:
   - 027X – Medical/Surgical Supplies and Devices; 0272 – Sterile
   - 036X – Operating Room Services; 0361 – Minor Surgery
   - 072X – Labor Room/Delivery; 0720 – General

2. **Field 44 – HCPCS/Rate/HIPPS Code:** Bill for the insertion of a cervical dilator using CPT code 59200 – Insertion of cervical dilator (e.g., laminaria, prostaglandin) (separate procedure. *Note: There is no CPT code and no separate payment for removal of Dilapan-S.*)

   Additional Examples used for HCPCS/Rate/HIPPS Code: CPT Code 59025 – Fetal non-stress test; Rate $80.00 cost per Dilapan-S cervical dilator rod.

3. **Field 45 – Service Date:** The date on which the indicated service was provided.

4. **Field 66 – DX (Diagnosis or Nature of Illness or Injury):** Apply appropriate diagnosis codes as required for reimbursement of CPT 59200.

   Examples used but not limited to: Z3A.40 – 40 Weeks gestation of pregnancy; Z37.0 – Single live birth.

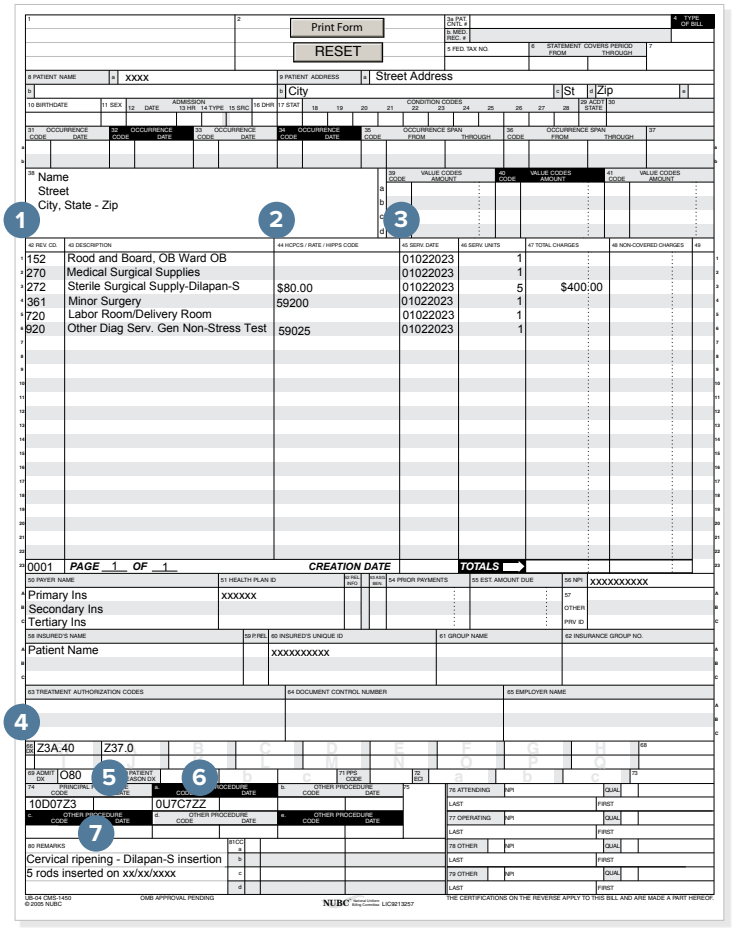
5. **Field 69 – Admit DX (Admitting Diagnosis):** Enter a valid ICD-10-CM Diagnosis, code to the highest level of specificity.

   Examples used but not limited to: O80 – Encounter for full-term uncomplicated delivery.

6. **Field 74 A-E – Other Procedure Codes and Dates:** Enter the appropriate ICD-10-PCS code identifying the secondary medical or surgical procedure.

   Examples used: OU7C7ZZ – Dilation of Cervix, Via Natural or Artificial Opening.

7. **Field 80 – Remarks:** This field is used to report additional information necessary to process the claim. Allow for "text" to include more information about the claim to the payer (e.g., identify Dilapan-S for cervical ripening).



If insertion occurs more than 24 hours prior to delivery, with appropriate modifier and documentation of medical necessity, CPT 59200 is reported separately (outside the Maternity Global Bundle).

Payers may require Medical documentation (e.g., medical dictation notes) supporting medical necessity for CPT 59200.

For illustrative purposed only. Example of billing claim form does not contain an exhaustive list of services which may be offered to a patient during the insertion service encounter. Place of service code depends on the site of care where procedure is performed. Diagnosis codes are based on the patient's condition. The physician is responsible for appropriate selection of procedure/service/treatment CPT/HCPCS codes.

Documentation

Medical record documentation is key to communicating essential information for making a decision as to whether a procedure was medically necessary for a particular patient.

Medical record documentation should convey information about a patient's medical condition, the rationale for the induction of labor procedure, and the outcome of the procedure.

See payer policy for specific documentation and medical coverage criteria.

Important Safety Information[1]

Indication for Use:
Dilapan-S® is for use by healthcare professionals trained in OB/GYN whenever cervical softening and dilation are desired, such as for cervical ripening during term labor induction or gynecological procedures that require cervical preparation.

Contraindication:
Dilapan-S® is contraindicated in the presence of clinically apparent genital tract infection.

Warnings & Precautions:

- Dilapan-S® is intended for single use only. **Do not** reuse, resterilize, reprocess, or use if primary packaging has been opened or damaged. Discard after use.
- Careful placement of the device is essential to avoid traumatic injury to the cervix or uterus (see Instructions for Use—Insertion). The device should not be left in place more than 24 hours. **Instruct patients to:** Report any excessive bleeding, pain, or temperature elevation, and to avoid bathing, douching, and intercourse. Patients should return to the healthcare provider for removal of Dilapan-S® at the indicated time and should be instructed not to attempt self-removal under any circumstances.
- Potential Complications/Risks: Twisting of device during removal may cause the device to break (see Instructions for Use—Removal). Complications may include: device entrapment and/or fragmentation, expulsion, or retraction; patient discomfort or bleeding; spontaneous rupture of membranes; spontaneous onset of labor; cervical laceration.

Storage & Handling: Store between +15°C and +30°C and keep away from direct sunlight and high humidity.

Please click here to download the Instructions for Use.

You are encouraged to report adverse events related to Dilapan-S® by calling 1 (888) 257-9676 or email USRegulatory@medicem.com. If you prefer, you may contact the U.S. Food and Drug Administration (FDA) directly. Visit http://www.fda.gov/MedWatch or call 1-800-FDA-1088.

References

1. Dilapan-S Instructions for Use. DSPlenus-Rev019/2021-04.
2. U.S. Food and Drug Administration. Dilapan-S. 510(k) – K143447. April 17, 2015.
3. Current Procedural Terminology 2023. CPT® copyright 2023 American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association. Applicable FARS/DFARS apply.
4. Calendar Year 2023 Medicare Physician Fee Schedule. Final Rule [CMS-1770-F]. Federal Register, November 18, 2022. Medicare physician national payment rates listed in this document are based on the 2023 PFS conversion factor of $33.0607. No geographic adjustments have been made to the reported payments.
5. Centers for Medicare & Medicaid Services, CMS 1500 Claim Form. The CMS-1500 form is the standard claim form used by a non-institutional provider or supplier to bill Medicare carriers and durable medical equipment regional carriers (DMERCs) when a provider qualifies for a waiver from the Administrative Simplification Compliance Act (ASCA) requirement for electronic submission of claims. Revenue Code; Chapter 25 Medicare Claims Processing Manual, Publication# 100-04; 75.4 - Form Locator 42 (Rev. 1973, Issued: 05-21-10, Effective: 09-01-10, Implementation: 09-01-10)
6. Calendar Year 2023 Medicare Outpatient Prospective Payment and Ambulatory Surgical Center Payment System. Final Rule [CMS-1772-FC]. Addendum D1. Federal Register, November 23, 2022.
7. Calendar Year 2023 Medicare Outpatient Prospective Payment and Ambulatory Surgical Center Payment System. Final Rule [CMS-1772-FC]. Addendum A and B OPPS APC. Federal Register, November 23, 2022.
8. Centers for Medicare & Medicaid Services Manual System Pub 100-04 Medicare Claims Processing Manual; Chapter 4 – Part B Hospital (Including Inpatient Hospital Part B and OPPS). https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS018912 Accessed: January 3, 2023.
9. Centers for Medicare & Medicaid Services ICD-10-PCS. 2023 ICD-10-PCS. https://www.cms.gov/medicare/icd-10/2023-icd-10-pcs Accessed: December 28, 2022.
10. Fiscal Year 2023 Medicare Inpatient Prospective Payment System. Final Rule [CMS-1771-F and CMS-1771-CN], Table 1A-1E Correcting Amendments and Table 5 MS-DRGs. Federal Register August 10, 2022, and December 13, 2022.
11. Centers for Medicare & Medicaid Services, CMS 1450 Claim Form. The CMS-1450 form (aka UB-04 at present) can be used by an institutional provider to bill a Medicare fiscal intermediary (FI) when a provider qualifies for a waiver from the Administrative Simplification Compliance Act (ASCA) requirement for electronic submission of claims.

