



Via email [PE\\_Price\\_Input\\_Update@cms.hhs.gov](mailto:PE_Price_Input_Update@cms.hhs.gov)  
[MedicarePhysicianFeeSchedule@cms.hhs.gov](mailto:MedicarePhysicianFeeSchedule@cms.hhs.gov)

Ms. Elizabeth Richter  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Mail Stop: C4-01-26  
7500 Security Blvd.  
Baltimore, MD 21244-1850

RE: **Potentially Misvalued Code: CPT 59200 Insertion of cervical dilator (e.g., laminaria, prostaglandin) and Request to update supply/equipment prices CPT 59200 Insertion of cervical dilator**

Dear Ms. Richter:

On behalf of Medicem Inc., we respectfully nominate CPT code 59200 as a potentially misvalued code and we request an update of the supply prices because currently the values do not reflect the practice expense (PE) associated with Dilapan-S.

Dilapan-S was first marketed and sold in the United States in 2002. On April 17, 2015, the United States Food and Drug Administration (FDA) expanded the indication for Dilapan-S to include “whenever cervical softening and dilation are desired,” such as cervical ripening prior to term labor induction, or cervical preparation for gynecological procedures, such as those requiring instrumentation. Dilapan-S is made from Aquacryl®, a firm, synthetic hydrogel that promotes cellular dehydration by absorbing moisture, softening the surrounding cervical tissue, and increasing the rod volume. Dilapan-S expands in diameter and dilates the cervical canal by exerting a radial pressure. This leads to the release of endogenous prostaglandins initiating collagen degradation and cervical softening and ripening.

As CMS may recall, Medicem, Inc. submitted a request to establish a new Level II HCPCS code to identify Dilapan-S as part of the second biannual 2020 coding cycle for non-drug and non-biological items and services. In its final HCPCS coding decision, CMS concluded that:

Dilapan-S is not suitable for coding in Level II HCPCS. It is our understanding that Dilapan-S would likely be included by the American Medical Association (AMA) Relative Value Scale Update Committee (RUC) as a supply in the existing CPT code(s).

In response to the CMS determination, we have reviewed the practice expense files for CPT code 59200, *Insertion of cervical dilator (eg, laminaria, prostaglandin)*, which is the procedure in which a physician typically uses Dilapan-S. It is clear that Dilapan-S is not currently included as a supply item for this procedure code. The following are the supply expenses currently captured in the PE relative value units (RVUs) for CPT code 59200:



Category	CMS Code	Description	Unit	Price	NF quantity
Kit, Pack, Tray	SA048	pack, minimum multi-specialty visit	pack	\$4.0507	1
Kit, Pack, Tray	SA051	pack, pelvic exam	pack	\$15.413	1
Gown, Drape	SB006	drape, non-sterile, sheet 40in x 60in	item	\$ 0.153	1
Gown, Drape	SB024	gloves, sterile	pair	\$ 0.8925	1
Wound Care, Dressing	SG055	gauze, sterile 4in x 4in	Item	\$0.1823	4
<b>Pharmacy, Rx</b>	<b>SH045</b>	<b>Laminaria tent</b>	<b>item</b>	<b>\$4.0683</b>	<b>3</b>
Pharmacy, NonRx	SJ041	povidone soln (Betadine)	ml	\$0.2587	50
Pharmacy, Rx	SH074	water, sterile for irrigation (250-1000 ml uou)	item	\$2.66	1

The only “Pharmacy, Rx” supply cost currently reflected in CPT code 59200 is for Laminaria, a dried sea grown plant, with a total price of \$12 for three units.

The list price for Dilapan-S is \$80 per rod. Typically, four rods are inserted, for an average Dilapan-S supply cost of \$320. We are submitting invoices demonstrating these costs for your reference. Thus, the typical supply cost associated with Dilapan-S far exceeds the national 2021 Medicare non-facility payment rate for CPT code 59200 (\$103.63).

We also note the clinical importance of ensuring that the Medicare PE valuation for CPT 59200 supports the use of Dilapan-S as an alternative to Laminaria.

We therefore formally nominate CPT code 59200 as a misvalued code on the grounds that: (1) “prices for certain high-cost supplies or other direct PE inputs that are used to determine PE RVUs are inaccurate and do not reflect current information” and (2) the code descriptor, which includes the product “Laminaria,” may not reflect current practice and therefore discourages physicians from reporting CPT 59200 when they use Dilapan-S.

We consulted with a data analytic expert to better understand if Dilapan-S or any drug/pharmacy supply was typically reported with CPT 59200. Specifically, the expert supplied the following information related to 2019 Medicare carrier data for CPT 59200:

- CPT code 59200 appears in the data 16 times.
- Because the carrier data is a 5% sample, he calculated there were approximately 320 Medicare physician claims (16 \* 20) for CPT 59200 in CY2019.
- CPT 59200 was reported as 1 unit
- No claims included multiple lines of CPT 59200
- CPT 59200 appeared by itself (with no other HCPCS codes) on fewer than 11 claims.
- The places of service where the codes appeared were:



- o Office
- o Inpatient Hospital
- o Outpatient Hospital
- o ASC

While we believe that CPT 59200 is misvalued, we also formally request that CMS update the supply inputs for CPT 59200 as quickly as possible. We encourage CMS to work closely with the AMA RUC and stakeholders to update the supply inputs and resulting PE RVUs for CPT code 59200 to reflect the cost of Dilapan-S to promote accurate valuation for this procedure. Specifically, we ask that CMS:

- Add Dilapan-S to the list of non-facility PE inputs
- Recognize a quantity of four rods
- Establish the unit as rods
- Per unit price is \$80
- Set the total dollar amount at \$320

Please let us know if you need any additional information, or if you have any questions about this request.

Thank you for your consideration.

Sincerely,

A handwritten signature in blue ink that reads "Tess Wong".

Tess Wong  
Director of Market Access & Reimbursement  
Medicem Inc.

cc: Leslie North, President & CEO  
Enclosures

**SPECIALTY PHARMACEUTICAL  
SERVICES**

**Invoice**  
Distributed by Specialty Pharmaceutical Services

Remit to:

MEDICEM INC- SPECIALTY PHARM SVCS  
EFT/ACH 826200649 RT 071000013  
LOCKBOX 28390  
28390 NETWORK PLACE  
CHICAGO, IL 60673-1283  
Telephone: 844-985-1368 Fax: 614-652-9760

HPSRX ENTERPRISES  
1640 ROANOKE BLVD  
SALEM VA 24153  
US

M46001

Invoice: 238  
Order: 1278  
PPS Number: 37100142  
Cust P/O: 01141147  
Terms: NET DUE 30 DAYS  
Ship Via: FedEx Ground  
Invoice Date: 01/28/21  
Due Date: 02/27/21  
Ship Date: 01/28/21

Ship To: M46101  
HPSRX ENTERPRISES INC  
1640 ROANOKE BLVD  
SALEM VA 24153  
US

LineItem	Ordered	Shipped	B/O UOM/NDC	Price	Amount
1 23170314810T	20.000	20.000	BX 23170314810	2,000.00	40,000.00
DILAPAN-S CERV DILATOR 4X65MM 25/CARTON					
Lot : DS190620465 QTY: 15.000					
DS290520465 QTY: 5.000					
2 23170312410T	20.000	20.000	BX 23170312410	2,000.00	40,000.00
DILAPAN-S CERV DILATOR 4X55MM 25/CARTON					
Lot : DS170620455 QTY: 1.000					
DS310320455 QTY: 19.000					
3 23170310010CAPT	10.000	10.000	BX 23170310010	230.00	2,300.00
DILAPAN-S CERV DILATOR 3X55MM 10/CARTON					
Lot : DS180220355 QTY: 5.000					
DS210220355 QTY: 5.000					

Total:	82,300.00
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MEDICEM INC MUST BE NOTIFIED OF ALL SHORTAGES AND/OR DAMAGES BY PHONE 844-985-1368 WITHIN 3 BUSINESS DAYS OF RECEIPT OF ORDER FOR CREDIT TO BE ISSUED. MEDICEM INC RETURN POLICY: RETURNS WILL ONLY BE ACCEPTED FOR CREDIT IN THE UNLIKELY EVENT OF PRODUCT DEFECT. FOR QUESTIONS OR COMMENTS, PLEASE CALL 844-985-1368. MEDICEM INC MUST BE CONTACTED WITHIN 3 CALENDAR DAYS FOR SHIPPING ERRORS AND WITHIN 24 HOURS FOR SHORTAGES.



# Invoice



**HPSRX ENTERPRISES INC**  
1640 Roanoke Blvd.  
Salem, VA 24153

Tel: 800-850-1657  
Fax: 800-361-6984

**Inv Number**

01600717

Page: 1

DEA Lic: RH0286662

Tax ID: 54-1945751

<b>Bill-to:</b> ANWH
ALLINA HEALTH SYSTEM AP PO BOX 1583 ATTN: ACCOUNTS PAYABLE MINNEAPOLIS MN 55440

<b>Ship-to:</b> 001 VR
ABBOTT NORTHWESTERN HOSPITAL 2800 10TH AVE RECEIVING DOCK/PO135642-0 MINNEAPOLIS MN 55407

<b>Invoice Date:</b>	01/26/21	<b>Salesman:</b>	CSR
<b>Ship Date:</b>	01/26/21	<b>Ship Via:</b>	UPS GROUND
<b>Our Order No:</b>	01228573001	<b>Purchase Order #:</b>	PO135642-0
		<b>Terms:</b>	Net 30 Days
<b>License</b>	HOSP EXEMPT Exp: 01/25/25		
<b>Special Instructions:</b>			

Line	Item Number / Description	Class	Ped	Shipped	UM	B/O Qty	Unit Price	UM	Extension
1	2410T DILAPAN- S CERV DILATOR 4 25/BOX	MR		1	BX	0	1800.00	BX	\$1,800.00
	<b>SUB TOTAL</b>								1,800.00
	<b>INVOICE TOTAL</b>								\$1,800.00
	<b>CARTON TRACKING NUMBERS:</b> CTN#1 1Z1E350W4241863401								
	1-TO OBTAIN A TI,TH,TS PLEASE VISIT OUR WEBSITE WWW. hpsrx.com								
	2- THIS WHOLESALE DISTRIBUTOR PURCHASED THE SPECIFIC UNIT(S) OF THE PRESCRIPTION DRUG(S) IDENTIFIED DIRECTLY FROM THE MANUFACTURER.								

<b>Cartons:</b> 1	<b>Weight:</b> 0.6
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\* Non-Taxable

\*\* REPRINT( 1) \*\*