

PAXMAN°



Paxman Scalp Cooling Procurement and Billing Guide

Your guide to the procurement process

Paxman offers two business models

01 –

Buy and Bill

Provider bills patient insurance

02 –

Self Pay

Patient pays out-of-pocket

This guide focuses on the **buy and bill business model**, and the steps in the procurement and billing process for Paxman Scalp Cooling.

Coding Guide

CPT Codes effective November 21, 2021:

- 0662T:** Scalp cooling mechanical, initial measurement and calibration of cap. This code is billed when the cap is fitted to the patient and may only be utilized one time per patient.
- 0663T:** Placement of device, monitoring, and removal of device. This code is billed each time the patient receives scalp cooling during chemotherapy and is to be used in conjunction with chemotherapy administration codes 96409, 96411, 96413, 96415, 96416, and 96417.

ICD-10-CM Diagnosis Codes

The Paxman Scalp Cooling System is indicated to reduce the likelihood of chemotherapy-induced alopecia (CIA) in cancer patients with solid tumors. Trials were conducted on patients who had solid tumors, such as ovarian, breast, colorectal and prostate cancers.

All diagnosis codes should correspond accurately to the patient's condition and at full discretion of the patient's physician.

Pre-requisites for scalp cooling reimbursement

Section 01

Determine if your site is contracted to the Paxman Buy and Bill model

If Yes: proceed to Section 02

If No: please contact reimbursement@paxmanusa.com to amend your contract

Section 02

Maintain Paxman cooling cap inventory

In order to transition to the Paxman Buy & Bill model you will need to have an account with McKesson. If you already have an account, you will still need to verify with them that this is the correct account, depending on your class of trade.

If you do not already have an account with McKesson they will have to complete an onboarding packet, and you should allow up to 4 weeks to have an account set up if you are not already contracted with McKesson.

Please make outreach to one of the listed McKesson parties to confirm if you already have an account or if you need to set up an account.

Follow your facility's process for obtaining a cap for the patient and placing an order for additional caps, by contacting the appropriate McKesson team based on your facility type:

Onmark and Unity

If you are a member of the Onmark or Unity GPO you will be able to purchase Paxman scalp cooling caps through these providers.

Please contact your account management.

Oncology Providers

McKesson Specialty Health

Phone: 800-482-6700**Email:** oncologycustomersupport@mckesson.com**Fax:** 855-824-9489**Online ordering portal:** mscs.mckesson.com**Multi-Specialty Providers**

McKesson Specialty Health

Phone: 855-477-9800**Email:** mshcustomerscare-mspl@mckesson.com**Fax:** 800-800-5673**Online ordering portal:** mscs.mckesson.com

MSCD Ordering Information

Material	Material Description
5503590	SCALP COOLING CAP KIT SMALL 1/EA
5503591	SCALP COOLING CAP KIT MEDIUM 1/EA
5503592	SCALP COOLING CAP KIT LARGE 1/EA
5503593	SCALP COOLING CAP KIT MEDIUM/SMALL 1/EA

Hospital, VA, Govt.

McKesson Plasma and Biologics

Phone: 877-625-2566**Email:** mpborders@mckesson.com**Fax:** 888-752-7626**Online ordering portal:** connect.mckesson.com

McKesson Plasma and Biologic Ordering Information

MPB Item No.	Selling Description
2393528	MPB COOLING CAP KIT SMALL
2393593	MPB COOLING CAP KIT MEDIUM
2393601	MPB COOLING CAP KIT LARGE
2393619	MPB COOLING CAP KIT MED/SMALL

Section 03

Enrol the patient in the Paxman Hub reimbursement program

- Enroll the patient in to the Paxman Scalp Cooling Program to check benefits/coverage via the Paxman Hub** - this form can be downloaded at paxmanscalpcooling.com/us-access-and-support
- Fax the completed form to the Paxman Hub on 888-358-0410**
- The provider will then receive acknowledgement of receipt of the Enrollment Form**
- When a provider office enrolls their first patient, they will receive a welcome call from the Paxman Hub to discuss the following:**
 - Verbal confirmation of enrollment form receipt
 - Review the program services and offerings
 - Discuss the next steps of the patient case
 - Address any questions the Prescriber may have
- Paxman Hub carries out the Benefits Investigation (BI) process**
- BI outcome results will be communicated to the Prescriber via a Summary of Benefits (SOB)**
 - See SOB example on the following page
 - If the benefits investigation confirms the patient is under- or uninsured the Hub will assess the patient for the Paxman Patient Assistance Program (PAP) - skip to Section 04 of this guide
- If Prior Authorization (PA) is required:**
 - Paxman Hub obtains PA forms, completes patient demographic information and provides to provider
 - Provider completes PA forms and sends back to payer
 - Paxman Hub follows up:
 - Paxman Hub communicates to Provider if PA is approved
 - Paxman Hub assists Provider through one appeal if PA is denied

Example Summary of Benefits:

PAXMAN[®]

Patient Summary of Benefits*

We have conducted a benefits investigation for your patient and received the following determination from **United Healthcare**

Primary Insurance Verification Results			
Patient Name:	Jane Smith	Payor Contact:	Brown L.
DOB:	01/01/1970	Payor Phone:	(111) 222-3333
Case ID:	1234567	Verification Completed on:	03/01/2023
Payor Name:	United Healthcare	Effective Date:	01/01/2023
Plan Type:	Point of Service (POS)	End Date:	01/01/2056
Policy Number:	987654321	Termination Date:	01/01/2056
In Network:	Yes		

Medical Benefits							
CPT 0662T & 0663T	Coverage for Scalp Cooling?	Co-pay:	\$ 50	Co- insurance:	%	Prior Authorization Required:	No
	Yes	Deductible (Individual):	\$ 500	Deductible Met:	\$ 500.00	Prior Authorization Next Steps:	
	Out-of- Pocket Max:	\$ 4500	Out-of- Pocket Max Met:	\$ 2588.36	Appeal Required:		

Notes
1234567: Patient has an active POS policy through United Healthcare. The Paxman cooling cap is a covered benefit. Per United Healthcare, CPT codes 0662T and 0663T are valid and billable. The deductible and out-of-pocket maximum does apply. The patient will have a \$50 co-pay per treatment. A Prior Authorization is not required.

For additional information, or if the patient has difficulty paying or acquiring their product, please contact Paxman Hub at 1-844-5PAXMAN (844-572-9626).

Thank you,

Paxman Hub

***THIS SUMMARY OF BENEFITS IS NOT A GUARANTEE OF COVERAGE OR PAYMENT. Payer coverage is subject to change without notice.**

Section 04

The Paxman Patient Assistance Program (PAP)

- For patients whose household income is 6x Federal Poverty Level (FPL) or below, they may be eligible for the Paxman PAP.

2024 FPL in 48 Contiguous States and the District of Columbia

Persons in Family/Household	FPL	600% FPL
1	\$15,060	\$90,360
2	\$20,440	\$122,640
3	\$25,820	\$154,920
4	\$31,200	\$187,200
5	\$36,580	\$219,480
6	\$41,960	\$251,760
7	\$47,340	\$284,040
8	\$52,720	\$316,320

For families/households with more than 8 persons, add \$5,380 for each additional person

2024 FPL for Alaska

Persons in Family/Household	FPL	600% FPL
1	\$18,810	\$112,860
2	\$25,540	\$153,240
3	\$32,370	\$193,620
4	\$39,000	\$234,000
5	\$45,730	\$274,380
6	\$52,460	\$314,760
7	\$59,190	\$355,140
8	\$65,920	\$395,520

For families/households with more than 8 persons, add \$6,730 for each additional person

2024 FPL for Hawaii

Persons in Family/Household	FPL	600% FPL
1	\$17,310	\$103,860
2	\$23,500	\$141,000
3	\$29,690	\$178,140
4	\$35,880	\$215,280
5	\$42,070	\$252,420
6	\$48,260	\$289,560
7	\$54,450	\$326,700
8	\$60,640	\$363,840

For families/households with more than 8 persons, add \$6,190 for each additional person

2. Standard information required for PAP consideration:

- ☐ Patient must sign to consent to participation in the program
- ☐ Patient must reside in the US
- ☐ Patient must have a physical US address
- ☐ Patient must have on-label diagnosis
- ☐ Patient must have a valid prescription for the covered product from a licensed Prescriber
- ☐ Prescriber and patient signature required on the Enrollment Form

ALL of the above criteria must be met before proceeding.

3a. Automatic qualification into the PAP

If EITHER of these criteria are met, that patient automatically qualifies into the PAP:

- Patient has an adjusted gross income of less than or equal to 600% of the Federal Poverty Level based on HHS
- and/or**
- Hardship waiver available if product is >50% of household income

3b. Conditional qualification into the PAP

- Patient must have no health insurance
- or**
- Patient must have no/not enough coverage (uninsured and underinsured patients)
- or**
- Patient has insurance but scalp cooling is not covered
- or**
- PA denied with no appeal available or first level appeal denied

4. If patient meets eligibility criteria, or is expected to meet eligibility criteria they will qualify for the Paxman PAP

The Paxman Hub will inform the Provider if the patient fully qualifies for the Paxman PAP and you will receive a free replacement cap to replenish your inventory from McKesson 3PL.

Have any questions?

For questions regarding procurement and billing, please contact the Paxman US Headquarters at reimbursement@paxmanUSA.com or by telephone on **8445 PAXMAN (844-572-9626)**

Our reimbursement FAQs can be found at www.paxmanscalpcooling.com

Resources

Provider information available at paxmanscalpcooling.com

Patient information and resources available at coldcap.com

PDF Downloads:

- Prior Authorization Checklist
- Claim Filing Checklist
- Letter of Appeals Checklist

Glossary of Terms

BI	Benefits Investigation
CMS	Centers for Medicare and Medicaid Services
FPL	Federal Poverty Level
HCPCS	Healthcare Common Procedure Coding System
ICD-10-CM	International Classification of Diseases, Tenth Revision, Clinical Modification
MAC	Medicare Administrative Contractor
(Medicare) AC	Administrative Contractors
OOP	Out of Pocket
PA	Prior Authorization
PAP	Patient Assistance Program
SOB	Summary of Benefits

Indication and Important Safety Information

Indication for use

The Paxman Scalp Cooling System is indicated to reduce the likelihood of chemotherapy-induced alopecia (CIA) in cancer patients with solid tumors

Intended use

The sale, distribution, and use of Paxman Scalp Cooling System is restricted to prescription use in accordance with 21 CFR §801.109.

The Paxman Scalp Cooling System is intended for use by appropriately qualified healthcare professionals who have been trained in correct operation of the device by a Paxman representative. You should be aware of the following:

- Hair loss is a possible side effect of chemotherapy
- The treatment success rates with the Paxman Scalp Cooling System vary from patient to patient and with different drug regimens being administered
- Patients cannot be guaranteed they will not lose any or all of their hair
- Patients may have a headache during treatment
- Some patients may feel cold during treatment
- Some patients may feel lightheaded after the Paxman Scalp Cooling Cap has been removed
- Patients may visit the restroom during treatment

Contraindications

Scalp cooling is contraindicated in pediatric patients.

Scalp cooling is contraindicated in patients:

- An existing history of scalp metastases or the presence of scalp metastasis is suspected
- Cancers of the head and neck
- CNS malignancies (either primary or metastatic)
- Cold sensitivity, cold agglutinin disease, cryoglobulinemia, cryofibrinogenemia, cold migraine, cold urticaria, and post-traumatic cold dystrophy
- Hematological malignancies (leukemia, non-Hodgkin and other generalized lymphomas) or hematological malignancies that are being treated for cure
- Imminent bone marrow ablation chemotherapy
- Imminent skull irradiation
- Previously received, or scheduled to undergo skull irradiation
- Scalp metastases have rarely been reported in the literature, but caution regarding their development has been a limitation for the broad-scale

application of scalp cooling during chemotherapy. Theoretically, tumor cells that have seeded in the scalp might not receive adequate chemotherapy during hypothermia, thus allowing them to grow at a later date

- Severe liver or renal disease from any etiology who may not be able to metabolize or clear the metabolites of the chemotherapeutic agent
- Skin cancers including melanoma, squamous cell carcinoma, and Merkel cell carcinoma
- Small cell carcinoma of the lung
- Solid tumors that have a high likelihood for metastasis in transit
- Squamous cell carcinoma of the lung

Warning and precautions

- Scalp and/or cutaneous metastases have been reported in patients with non-small cell lung cancer, colon cancer, renal cell carcinoma, ovarian cancer, and bladder cancer. Patients with advanced forms of these tumors may be more likely to experience scalp metastases with the scalp cooling system
- It cannot be guaranteed that scalp cooling will prevent all patients undergoing chemotherapy from losing any or all their hair. The success rate of scalp cooling in reducing chemotherapy-induced hair loss varies from patient to patient and according to the chemotherapy regimen administered
- Long-term effect of scalp cooling and scalp metastasis have not been thoroughly studied
- Use of scalp cooling in the palliative setting in patients with metastatic cancer may also increase the risk of scalp metastases
- Use of scalp cooling with taxanes plus anthracyclines when used together in sequence has not been shown to be successful in preventing chemotherapy drug-induced alopecia. The Paxman Scalp Cooling System should not be used in these patients
- The effectiveness of this device in patients who have received previous chemotherapy has not been evaluated
- Clinical studies have demonstrated variable success rates in patient reduction of chemotherapy-induced alopecia with scalp cooling since the outcome is dependent on multiple factors including chemotherapy regimen, dose, duration of drug infusion, chemotherapy drug metabolism, and concomitant comorbidities. Data has shown that women who experience hair loss despite using scalp cooling might have worse quality of life than women who did not have scalp cooling
- The Paxman Scalp Cooling System should only be used by appropriately qualified healthcare professionals who have been trained in the operation of the device
- Do not allow any liquids to be placed on the scalp cooler or near the touch screen controller, including drips from the cooling caps
- Avoid use in ambient temperatures of over 30°C/86°F
- Do not touch the side ventilation grills whilst the device is in use

If you have any questions, please reach out to:

Paxman Hub

Open Monday - Friday 8am - 8pm EST

Tel **8445 PAXMAN (844-572-9626)**

Self-pay: patient payment

Buy and Bill: missing enrollment form information for Benefits Investigations

Paxman US Headquarters

Open Monday - Friday 8am - 5pm EST

Tel **888 572 9626**

Self-pay: patient receipts, shipping information