

PAXMAN SCALP COOLING PROCUREMENT AND BILLING GUIDE

- YOUR GUIDE TO THE PROCUREMENT PROCESS

If you have any questions, please reach out to the Paxman HUB

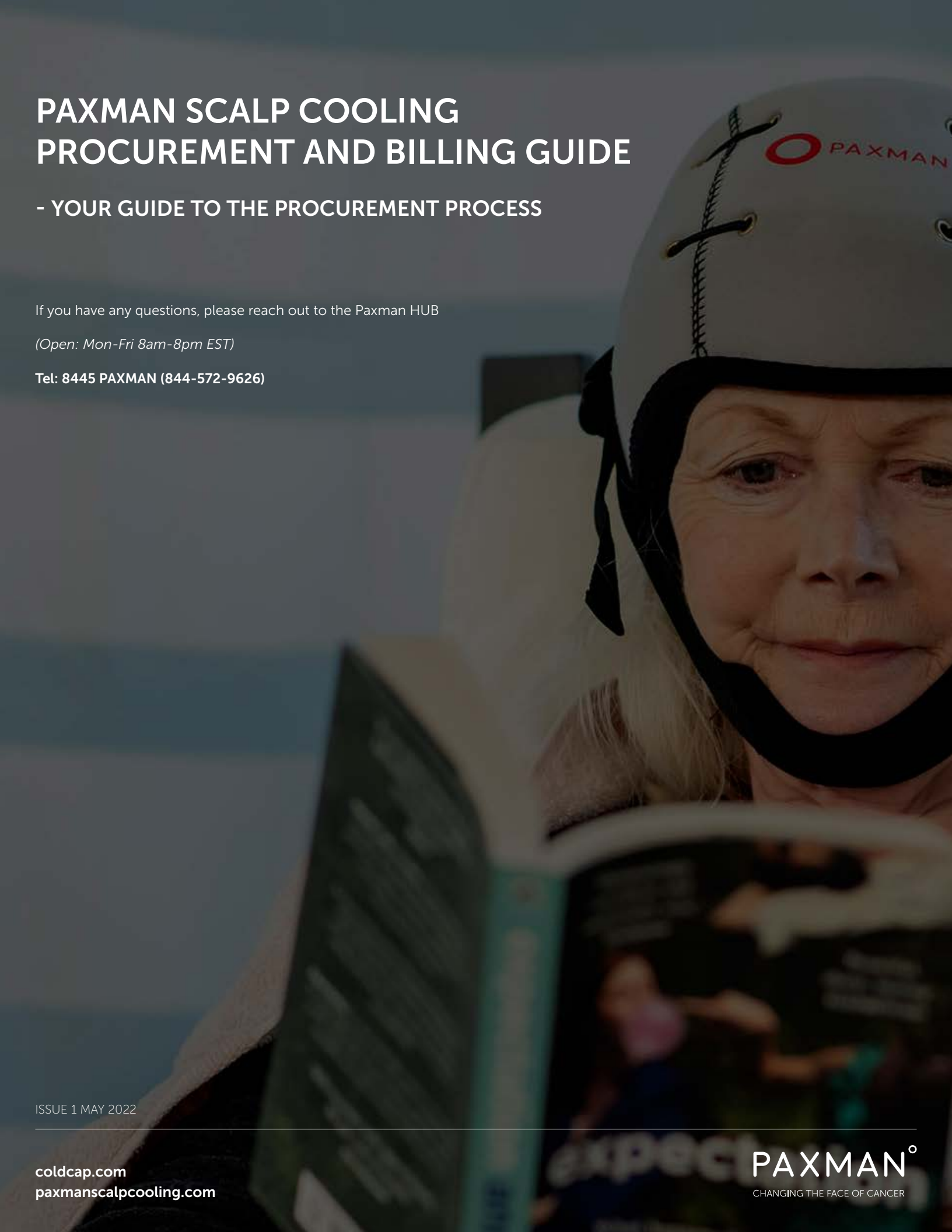
(Open: Mon-Fri 8am-8pm EST)

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coldcap.com
paxmanscalpcooling.com

PAXMAN^o
CHANGING THE FACE OF CANCER



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 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 with:

- 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

Warnings 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 effects 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 for scalp metastases
- Use of scalp cooling with Taxanes plus anthracyclines when used together or in sequence has not been shown to be successful in preventing chemotherapeutic 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 have 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



PAXMAN SCALP COOLING CAN BE FUNDED/ ACQUIRED THROUGH MULTIPLE OPTIONS

- Procurement through McKesson
- Procurement through patient Self Pay

This guide focuses on the McKesson procurement option specifically

How to Use This Guide

This guide is organized chronologically detailing the specific steps in the procurement and billing process and what to expect at each stage. Each section contains helpful information, key considerations, and frequently asked questions (FAQs). Whether you're new to scalp cooling or just need a quick refresher on the process, keep this guide handy to refer to whenever questions come up.

Have more questions?

Reach out to your Paxman access and reimbursement contact using the information provided on the cover of this guide.

Renee Jernander , Market Access & Reimbursement Manager - US

Renee@PaxmanUSA.com

813-240-1505

PRE-REQUISITES FOR SCALP COOLING

Prior to offering Scalp Cooling as an available service to a patient your practice /location must already have contracted with Paxman and installed Paxman Scalp Cooling Units.

If you have not installed these units please contact

Tel: 8885 PAXMAN (888-572-9626)

HCP@paxmanUSA.com



STEP ONE – DETERMINE IF YOUR SITE PARTICIPATES IN THE PAXMAN BUY AND BILL MODEL INCLUDING FULL HUB REIMBURSEMENT AND PATIENT ASSISTANCE PROGRAM (PAP) SERVICES

- If Yes – proceed to step two
- If No – if you are interested in participating please contact hcp@paxmanusa.com to amend your contract. If your patient prefers to self-pay, instructions are located on coldcap.com here.

STEP TWO – ORDERING THE CAP

1. Your facility should have an inventory of caps, follow your facility’s process for obtaining a cap for the patient and placing an order for a replacement cap
2. Contact the appropriate McKesson team based upon your facility type

Hospital, VA, Govt. McKesson Plasma and Biologics:
 Phone: 877-625-2566
 Fax: 888-752-7626
 Email: mpborders@mckesson.com
 Online ordering portal: connect.mckesson.com

Oncology Providers McKesson Specialty Health
 Phone: 800-482-6700
 Fax number: 855-824-9489
 Email: oncologycustomersupport@mckesson.com
 Online Ordering Portal: mscs.mckesson.com

Multi-Specialty Providers McKesson Specialty Health
 Phone: 855-477-9800
 Fax number: 800-800-5673
 Email: mshcustomercare-mspl@mckesson.com
 Online Ordering Portal: mscs.mckesson.com

3. Order the cap for the patient using the following material numbers

MSCD

Mat #	Description
5503590	SCALP COOLING CAP SMALL 1/EA
5503591	SCALP COOLING CAP MEDIUM 1/EA
5503592	SCALP COOLING CAP LARGE 1/EA
5503593	SCALP COOLING CAP MEDIUM/SMALL 1/EA

McKesson Plasma and Biologics

MPB Item Number	Selling Description
2393528	MPB COOLING CAP SMALL
2393593	MPB COOLING CAP MEDIUM
2393601	MPB COOLING CAP LARGE
2393619	MPB COOLING CAP MED/SMALL



STEP THREE – ENROLLING PATIENT IN PAXMAN FULL HUB REIMBURSEMENT AND PATIENT ASSISTANCE PROGRAM (PAP) SERVICES

1. Provider to complete Paxman HUB enrollment form (see below information on PAP)

- a. <https://paxmanscalpcooling.com/wp-content/uploads/2022/05/Paxman-Hub-Enrollment-Form-0422.pdf>

2. Provider to fax completed form to Paxman HUB

- a. 888-358-0410

3. Provider receives acknowledgement of receipt of form

4. Provider receives welcome call from Paxman HUB

- a. HUB will call Prescriber after receipt of enrollment for a Prescriber Welcome Call. HUB will discuss the following during the Prescriber Welcome Call:
 - i. Verbal confirmation of enrollment form receipt
 - ii. Discuss missing information, if applicable
 - iii. Review the program services and offerings
 - iv. Discuss the next steps of the patient case
 - v. Address any questions the Prescriber may have

5. Paxman HUB Completes BI Process

- a. Paxman HUB checks the following:
 - i. Patient Coverage?
 1. If patient is uninsured, skip to steps 7-9 below
 2. Medical
 - a. Deductible met, and OOP met
 - b. Deductible max, and OOP max
 - c. Plan effective date
 - d. Copay / Co-Insurance
 - e. Commercial or Government plan; self-funded or fully funded
 - f. Calendar or fiscal year plan
 3. Is a Prior Authorization (PA), Predetermination, Step Edit or Precertification required?
 4. Is Prescriber in network?
 5. Is the Infusion Center in network? Tax ID of the Infusion Center would be required.
 - ii. BI outcome results will be communicated to the Prescriber utilizing fax and telephone
 - iii. HUB will call Prescriber after faxing Summary of Benefits (SOB) to review and discuss findings
 - iv. If Prior Authorization is required:
 1. Paxman HUB obtains Prior Authorization forms and provides to provider
 2. Provider completes Prior Authorization forms and sends back to payer
 3. Paxman Hub follows up
 - a. If prior authorization approved Paxman Hub communicates to provider
 - b. If prior authorization is denied Paxman Hub assists provider through two appeals

6. Possible Outcomes of BI Process

- a. Patient covered fully by commercial insurance
 - i. Provider to submit claim to insurance as usual
- b. Patient covered fully by government plan
 - i. Provider to complete CMS form 1450 upon completion of first treatment and cap fitting
- c. Patient covered partially by commercial insurance
 - i. Once co-pay program is active, patient will be assessed for qualification
- d. Patient covered partially by government plan
 - i. Patient referred to foundation support to see if funding available to cover remaining cost
- e. Prior Authorization or appeal required (see prior step)
 - i. If successful revert to 7.a. above
 - ii. If not successful:
- f. Patient not covered by insurance:
 - i. May qualify for Patient Assistance Program (see steps 7-9)
 - ii. May qualify into co-pay assistance program
 - iii. Or will qualify for patient self-pay (see Step two)



7. For Patients whose household income is 6x FPL or below they may be eligible for the Paxman Patient Assistance Program

a. Criteria for eligibility is as follows:

2022 Federal Poverty Levels (FPL) in 48 Contiguous States and the District of Columbia

Household Size	FPL	600% FPL
1	\$13,590	\$81,540
2	\$18,310	\$109,860
3	\$23,030	\$138,180
4	\$27,750	\$166,500
5	\$32,470	\$194,820
6	\$37,190	\$223,140
7	\$41,910	\$251,460
8	\$46,630	\$279,780

2022 Federal Poverty Levels for Alaska

Household Size	FPL	600% FPL
1	\$16,690	\$100,140
2	\$22,890	\$137,340
3	\$28,790	\$172,740
4	\$34,690	\$208,140
5	\$40,590	\$243,540
6	\$46,490	\$278,940
7	\$52,390	\$314,340
8	\$58,290	\$349,740

2022 Federal Poverty Levels for Hawaii

Household Size	FPL	600% FPL
1	\$15,630	\$93,780
2	\$21,060	\$126,360
3	\$26,490	\$158,940
4	\$31,920	\$191,520
5	\$37,350	\$224,100
6	\$42,780	\$256,680
7	\$48,210	\$289,260
8	\$53,640	\$321,840



STANDARD INFORMATION REQUIRED:

ALL of these criteria HAVE to be met, before proceeding:

- Patient must provide consent to participate 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

AUTOMATIC QUALIFICATION INTO THE PAP:

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

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

CONDITIONAL QUALIFICATION INTO THE PAP:

For these criteria it may not be possible to ascertain whether or not the patient has met these criteria until their enrollment form is assessed by the Paxman HUB and the Benefits Investigation has been completed. As such the following conditions do NOT need to be met before proceeding to the next step.

- i. Patient must have no health insurance (OR)
 - 1. Patient must have no/not enough coverage (Uninsured and underinsured patients) (OR)
 - a. Patient has insurance but covered product is not covered (OR)
 - i. PA denied with no appeal available or 2nd level appeal denied
 - b. If patient meets eligibility criteria, or is suspected to meet eligibility criteria, proceed to next step
 - c. If patient does not meet eligibility criteria refer to self-pay model/ foundation support

8. Full qualification into PAP program

- a. If the patient qualifies fully into the PAP program you will be informed by Paxman HUB and you will receive a free replacement cap to replenish your inventory from McKesson 3PL

9. Foundation Assistance steps

- a. The patient will be referred to foundation support
- b. The Foundation may either:
 - i. Grant funding directly to the patient, if they qualify, in which case the patient becomes a self pay patient (see Step Two on page 6)
 - ii. OR Grant funding to you, the provider, if they qualify

10. Copay Assistance Program under construction



ADMINISTERING SCALP COOLING

FAQs

Why is Paxman offering a new business model and encouraging providers to bill insurance?

- Currently, scalp cooling is only available to those who have the financial means to pay out-of-pocket or those who are fortunate enough to get foundation assistance or grants. Because retaining hair is so important to so many people, Paxman would like to make scalp cooling more available by including provider-billed insurance as an option.

Does my practice have to participate in the new business model?

- No, participation in the new business model is completely optional. The reason for doing so is to offer scalp cooling to patients who are unable to self-pay. If you wish to participate in the new business model, a simple addendum to your contract is offered by Paxman.

Can my practice offer both self-pay option and the new business model?

- Yes. Your practice may allow some patients to continue to self pay and bill insurance for other patients. Offering a hybrid model is an option and Paxman will contract with you accordingly.

What if my patient does not qualify for the PAP program?

- They will be directed to self-pay and / or foundation assistance.

Who do I contact with questions about patient access/ reimbursement?

- Renee Jernander , Market Access & Reimbursement Manager - US
- Renee@PaxmanUSA.com
- 813-240-1505

How do I get caps under the new business model?

- You will purchase from McKesson- either directly of through your group purchasing organization.

What's the contact information for Paxman HUB?

- 8445 PAXMAN (844-572-9626)
- Fax 888-358-0410

Patient Care/Resources available to providers at Paxmanscalpcooling.com and patients at Coldcap.com

