



I've decided to scalp cool, tell me what I need to know

Scalp cooling patient manual

The start of scalp cooling

You are now at the beginning of your scalp cooling process. We hope the journey will be smooth, but we are here to support you through your experience and help with any challenges ahead. The following, in conjunction with coldcap.com, will guide you through all the information you will need to know to make the most of your scalp cooling treatment.



For detailed information, FAQs and support visit our online patient platform,

coldcap.com

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I was determined to learn as much as I could about scalp cooling in the spirit of saving my hair.

Angela

Getting ready for scalp cooling

Getting ready for scalp cooling and chemotherapy can feel overwhelming, but it is important that you put some time aside to get yourself prepared for scalp cooling.

Now that you have made your decision, there are some key bits of information that you will need to familiarize yourself with

Get to know the cap and practice putting it on

Putting your cap on properly is the most important thing you can do to get the most from scalp cooling. Our 'How-To' videos (which we will take you to shortly) will show you exactly how to achieve this. You will need to put the cap on yourself, or with help from a friend or loved one – putting on the cap is not the responsibility of your clinical team. Taking ownership of this process is important - no-one will be more invested in getting the cap on properly than you are.

Think about your hair preparation

Particularly if you have curly or coily hair. Practicing in advance will make things easier on the day. We have another 'How-To' video that will walk you through your hair preparation.

Get to know about scalp cooling haircare

It won't make a difference to the amount of hair you might retain, but it will make your day-to-day care experiences easier, and make sure your hair is in the best condition possible. You'll find everything you need to know in the haircare booklet in your Cap Kit and at coldcap.com/haircare

Get to know what a realistic outcome will be for your regimen

Seeing what you are likely to face can be a little scary, but it is also a fundamental part of being realistic in your expectations. More on this shortly.

Find out more at

coldcap.com/getting-ready-for-scalp-cooling

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Cap kit

You will receive your Cap Kit before you begin your treatment. The Cap Kit contains everything you will need to scalp cool, and you will need to bring it with you to every chemotherapy session.

Getting to know the contents of the kit is an important part of scalp cooling preparation and will help to take away some of the uncertainty from your first treatment day.

Practicing putting on your cap ahead of your treatment is one of the most important things you can do to get the most from your treatment.

Watch the 'How-To' videos all the way through and practice putting on your cap **three times**. This will allow you to be confident with the cap and achieving a close and consistent contact between your scalp and the cap by the time you arrive at the hospital for your first treatment.

Choosing to become informed about the scalp cooling process can give you a feeling of confidence and control. Start your treatment positively by becoming as familiar as you can with the guidance in this patient manual, particularly the How-To videos.

The videos will give you confidence that you know what a good cap fit should look and feel like, and that you feel empowered about the care you need to give yourself between treatment days.

Within the Cap Kit you will find the following -

Your cooling cap

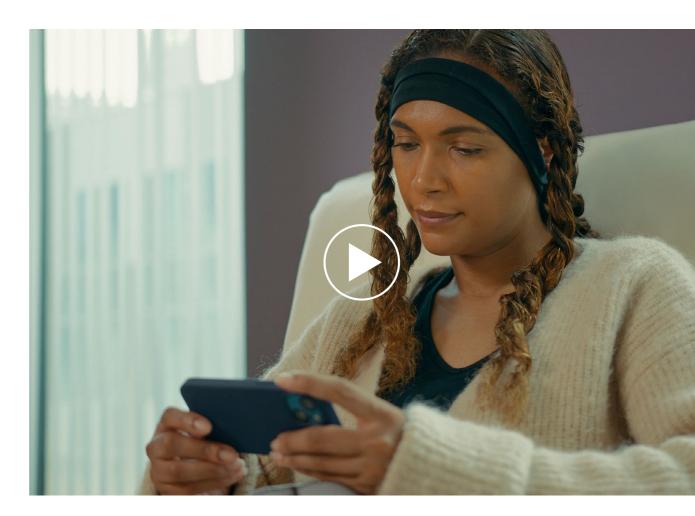
This will be the size decided upon at the fitting session with your clinician. It is made up of two sections – a blue silicone inner cap and a grey neoprene outer cover

Hair preparation kit

This includes a brush and comb, a spray bottle, a small towel, and a bottle of conditioner. You will need these items to prepare your hair ahead of scalp cooling

Education materials

This includes this patient manual which will give you advice and guidance on your scalp cooling treatment, a haircare guide, and information on how to care for your cap



What to expect

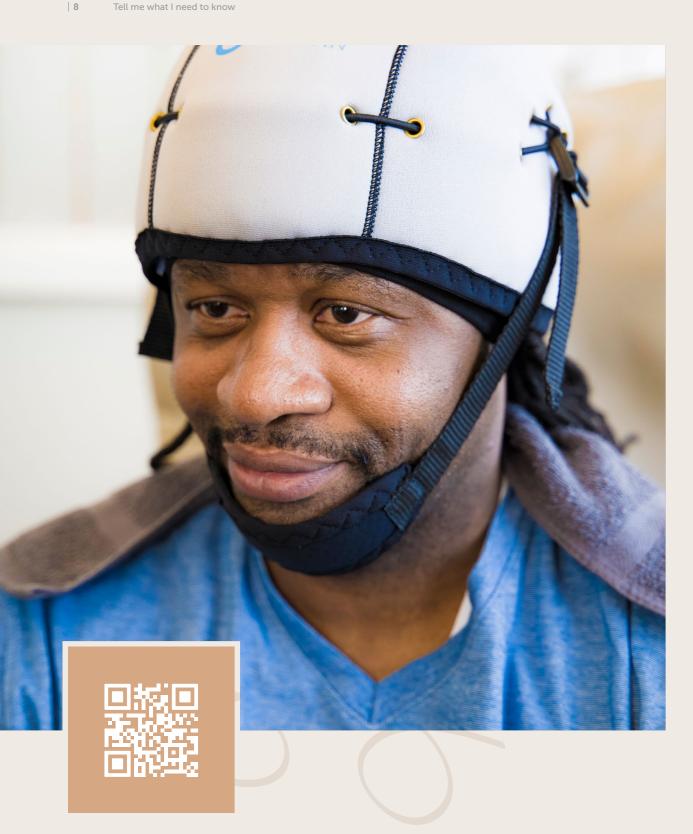
For most people, the first day of chemotherapy treatment can be scary.

There are a lot of things to think about and often lots of unanswered questions that can cause a feeling of anxiety. We have created a video that will help to explain the scalp cooling process, what you can expect, and help you to feel a little more prepared for what is coming, though remember that every hospital does things a little differently.

You will find the video at coldcap.com/what-is-scalp-cooling

If you have any questions about your chemotherapy treatment or the scalp cooling process, get in touch with your clinical team. They will be able to give you specific information about what you should expect.







Being realistic in your expectations of scalp cooling

The best thing you can do to set yourself up for a positive scalp cooling journey is to be realistic about your potential scalp cooling outcomes.

Having really high expectations is completely understandable, but if your hopes aren't built on evidence and the experiences others have had on similar regimens, then you could be setting yourself up for disappointment. The classic saying - prepare for the worst, hope for the best - will serve you well.

Find out more at

coldcap.com/realistic-expectations

Scalp cooling outcomes calculator

We have developed a calculator that will give you an indication of the amount of hair retention you could expect, based on the chemotherapy regimen you will be receiving. If you know your dosage you will get a more accurate indication.

The calculator uses information from the Dutch Scalp Cooling Registry which is a collection of information from over 7000 patients who have scalp cooled. It's the biggest scalp cooling data set in the world. The information is a true representation of scalp cooling with real patients in real cancer centers, rather than in a clinical trial setting. Access to so much data means that the calculator can give a reliable indication of what you can expect. It is important to remember that the calculator will only provide an indication of what has been experienced by others - you may see more or less hair retention, but it's a good starting point.

You will also see that the calculator generates the appropriate post-infusion cooling time for your regimen. There can sometimes be some confusion around these times, but the times generated by the calculator are those that we would recommend to get the best possible outcomes with that regimen.

You can access the outcomes calculator at coldcap.com/outcomescalculator

An indication of potential hair retention is a starting point, but you can also learn a lot from other people's experiences. The best place to do this is our private Facebook Group. It is a positive and supportive community of people from all over the world who are or have scalp cooled. They share their experience, questions, advice and support, and will give you a good understanding of what scalp cooling is really like.

You can join the Facebook Group at facebook.com/groups/ paxmanscalpcooling



Join the Paxman Facebook community



Use the scalp cooling outcomes calculator



There are no guarantees

This can be hard to accept, but sadly there are no guarantees with scalp cooling. As a result, scalp cooling isn't the right option for everyone.

Most patients who chose to scalp cool believe it was the right choice, even if they didn't see the retention they might have hoped for.

For some people it's an easy decision, but if you are feeling uncertain, it is good idea to give it a try. You don't have to commit to scalp cooling for all your treatments – take it one step at a time. If it feels ok after your first treatment, then you can try it

again with your second infusion. If at any point you don't want to carry on, you can stop. If it's not for you, then at least you won't be left wondering what could have been.

By choosing scalp cooling you are doing everything you can to help to manage chemotherapy-induced hair loss and to encourage faster and healthier hair regrowth.

If you want to know more about why there are differing scalp cooling outcomes for different people, please visit coldcap.com/realistic-expectations

How do I get the most from scalp cooling?

It is easy to think of scalp cooling as something that happens to you. To get the most from scalp cooling, it is important to think of the process as something you are proactively a part of.

The more you can get involved, engage with the treatment, and trust the process, the more empowered you will feel about scalp cooling. You are already off to a flying start by engaging with this information.

There are lots of elements that come together throughout the scalp cooling process that can affect the amount of hair you may retain - some can be managed, and others will be out of your control.

Making sure that you do your best to follow guidance on the things you can control will give you the best possible outcome, but it is still important to remember that there are some things you won't be able to influence.

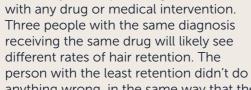
Factors out of your control

Chemotherapy drug and regimen

Your doctor will prescribe the best treatment plan for your diagnosis.

Individual biological response

Each person's body will respond differently to scalp cooling, as it does different rates of hair retention. The person with the least retention didn't do anything wrong, in the same way that the person with the most retention didn't do things better.





Before scalp cooling, I did tonnes of research. The Facebook Group was a lifeline, the advice and tips were invaluable before heading to treatment.

Charlotte

Find out more at

coldcap.com/get-the-most-from-scalp-cooling



Factors that can be controlled

Using the right size of cap

A close fit of the cap across your scalp will ensure the best possible outcome. You will be fitted for your cap by your clinical team to ensure you have the right size. A cap that is too small or too large can result in areas of your scalp not being in contact with the cap effectively, which will lead to hair loss.

Accurate cooling times

It is important that you receive the right amount of cooling both before and after the infusion of your chemotherapy drugs to get the most from scalp cooling. Your clinical team are responsible for these times. Pre-cooling of 30 minutes (45 minutes if your hair is thick) should occur before any chemotherapy drugs are infused. This ensures that your scalp is at the optimum temperature before the drugs reach your scalp.

Once all alopecia-causing chemotherapy drugs are infused, the post-cooling time can begin. This varies a little depending on the drugs you are receiving but is generally 90 minutes. This ensures your scalp is protected while the drugs are at their most potent within your body.

Scalp cooling practice may vary from hospital to hospital due to decision making at each cancer center. Paxman pre- and post-cooling times are based on extensive quantities of published clinical data and are the times we would recommend complying with for optimum results.

Finally, there are a few things that you can do to make sure that scalp cooling is as effective as possible:

Hair preparation

Preparing your hair properly will help to make sure the cap is in consistent contact across your scalp, making it easier for the heat to travel away from your scalp.

Putting the cap on properly

Making sure you have close and consistent contact between the cap and your scalp is the most important thing you can do to get the best possible outcomes. Putting the cap on properly doesn't need to be a complicated process, our 'How-To' video will walk you through it. The more you can practice before vour treatment the better. It is important to know what a good cap fit looks and feels like. The more you know about cap fitting the more confident you will feel. Take your time with cap fitting and don't be afraid to start again if you feel the cap could be put on better.



Support while you scalp cool

Having a support network in place while you are going through treatment is an important part of feeling comfortable and as resilient as possible when you are facing real challenges.



If possible, find someone who can come with you to your treatment, to keep you company and to help you with putting the cap on. Whether a friend, a loved one or family member, share as much information with them as you can – the more they know the more they will be able to support you. Send them the link to the website and get them to watch the How-To videos.

Don't forget about the scalp cooling community too – the support of others all over the world who are also going through scalp cooling can be invaluable.

Don't be afraid to ask for help and support.



Haircare

Looking after your hair well while scalp cooling won't make a difference to the amount of hair you could retain, but it will have an impact on your day-to-day experience.

Making some changes to your haircare routine will make it as easy as possible to look after your hair and will make sure that the hair you do retain is in the best possible condition at the end of your treatment.

We have all the guidance you will need on how to care for your hair either in the haircare booklet that was included in your Cap Kit or at **coldcap.com/haircare**

Things you might need

The only essentials for scalp cooling are the cap and cover, and some conditioner to help with hair preparation, all of which you will find in your Cap Kit.

In addition, there are a few things that you may want to consider that can make your day-to-day experience between chemotherapy and scalp cooling treatments a little easier. None of these are required, but we know those going through scalp cooling have found some of the following to have been helpful on the days between treatment.

Hypoallergenic shampoo and conditioner

If possible, a product that is hydrating and designed for dry or damaged hair.

A detangling brush and/or a wide tooth comb

Brushing your hair regularly is an important part of looking after your hair while scalp cooling, no matter which hair type you have. It's ok to use whatever kind of brush you think works best for your hair.

Conditioning products such as a hair mask, leave-in conditioner and natural oils

Chemotherapy treatment will dry out your hair and scalp. Conditioning products will help to keep your hair in the best possible condition and will aid brushing, washing, and over-all manageability.

A silk pillowcase or sleep cap

Your hair can become very prone to knotting and tangling due to friction between your hair and the pillowcase as you move in your sleep. Silk causes significantly less friction than a traditional cotton or linen pillowcase and can help to keep your hair more manageable.

Hair fibers or root touch up spray

Not everyone needs this, but if you do experience some patchy hair loss, these products can make a significant difference when trying to disguise thinning.

A head covering, topper or wig

Lots of people find comfort in having a wig or some kind of head covering before they start chemotherapy. There is no reason at all why you can't wear a wig when you are scalp cooling, if it doesn't cause tension or friction at the roots of your hair. It can be useful to get you through an occasion or a rough day. Wigs can be costly, so if you are uncertain, it may be worth waiting to see if you feel you need one, as not everyone does. Another option is a topper, like a wig but smaller, that can help to hide hair loss at the crown.







'How-to' videos

We have created a whole library of scalp cooling how-to videos to guide you through the most important parts of scalp cooling.

Please spend some time getting familiar with our step-by-step videos and get to know the guidance on which size of cap you may need, how to prepare your hair for scalp cooling, how to put the cap on correctly, and some hints and tips that can make scalp cooling easier.

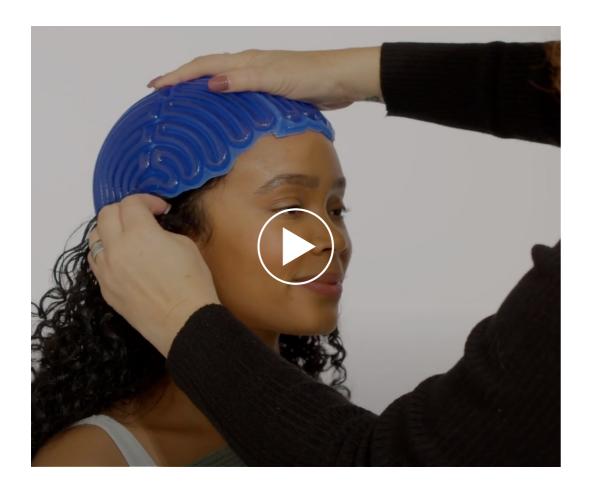
The more familiar you are with these videos and the process they outline, the more comfortable and confident you will feel at your first treatment.

- Sizing the cold cap
- Hair preparation for scalp cooling
- Putting on the cold cap
- Hints and tips

Find out more at

coldcap.com/how-to-videos

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Sizing the cold cap



Sizing the cold cap is the first step of the scalp cooling process and will be done for you by one of your clinical team.

The video will guide you through the steps so you know how the ideal cap fit should look and feel. Remember you are looking for a snug all over fit which means the cap is in close and consistent contact with your scalp.

Hair preparation for scalp cooling



Hair preparation is an important part of scalp cooling as it lays the foundations for a close and consistent cap fit, which in turn will give you the best possible outcome and hair retention.

With hair preparation we are aiming to achieve 3 key things:

- 1. Smoothing down your hair across your scalp to reduce the volume, getting rid of any air pockets.
- 2. Using water to help increase conductivity, ensures that it is as easy as possible for heat to transfer away from your scalp.
- 3. Using conditioner to ensure that the cap is easy to remove

Achieving these three key points changes a little based on your hair type and thickness, and can be done in several ways, but it is important to remember that as long as you are achieving the above three points, then there is no wrong way of doing hair preparation.



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Putting on the cold cap

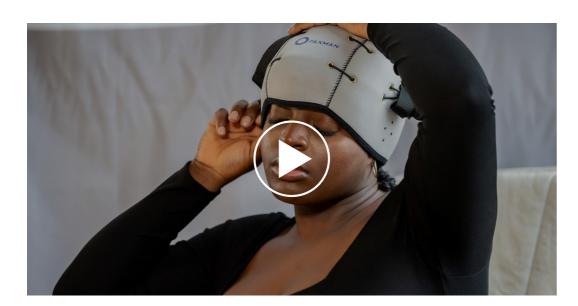
Putting on the cold cap properly before each treatment is the most important thing you can do to ensure the best possible outcome from scalp cooling.

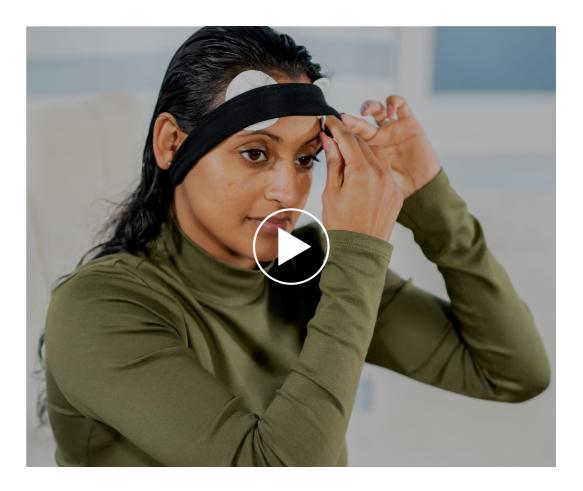
Putting on the cap doesn't need to be complicated. The video will explain step-by-step how you can get the cap on perfectly. The video will outline how to fit the cap on yourself, or how the cap can be fitted on someone else, so whether you are flying solo, or have the support of a friend or loved one, the video will give you all the information you will need.

There are three things to achieve when putting on the cap:

- 1. Consistent all over contact between your scalp and the inner cap
- 2. The inner cap and cap cover positioned centrally on your head
- 3. The bungee cords and the chin strap on the cap cover securely tightened, but not over tightened

Please watch the videos at least three times, so that you are familiar with the process and will be comfortable and confident for your first treatment.



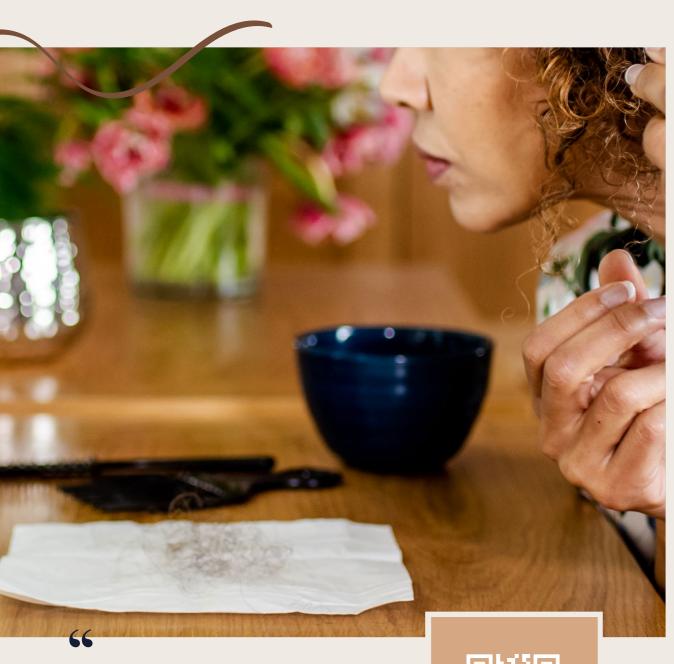


Hints and tips

Watch for little bits of wisdom that are simple and achievable and will help to make your cold capping experience as comfortable as possible.



The realities of scalp cooling



Of course, it would have been ideal to retain 100% of my hair. But, being prescribed Taxotere that can cause permanent hair loss, I am happy to retain roughly 40% of my hair and now 9 months later, I have extremely fast

hair regrowth.

Meredith

The realities of scalp cooling

Scalp cooling can have amazing results, but it can also be a challenging experience, even for those that see the highest levels of hair retention.

It would be easy to pretend that it will be simple, but it is important that we are honest and open about what you may experience on your scalp cooling journey. The private Facebook Group is a great place to get a full understanding of the scalp cooling experience from people going through it. If you haven't joined yet, it really is worth considering.

You can join the Facebook Group at facebook.com/groups/ paxmanscalpcooling

Try to channel a positive mind set and remember that while scalp cooling can be tough, the majority still believe it was the right choice for them.

This section will highlight some of the harder realities of scalp cooling. Understanding the potential challenges that come with scalp cooling will help you to have a realistic view of how treatment could go. We hope that this information won't be something you need, but it is here if you do.

Find out more at

coldcap.com/realities-of-scalp-cooling

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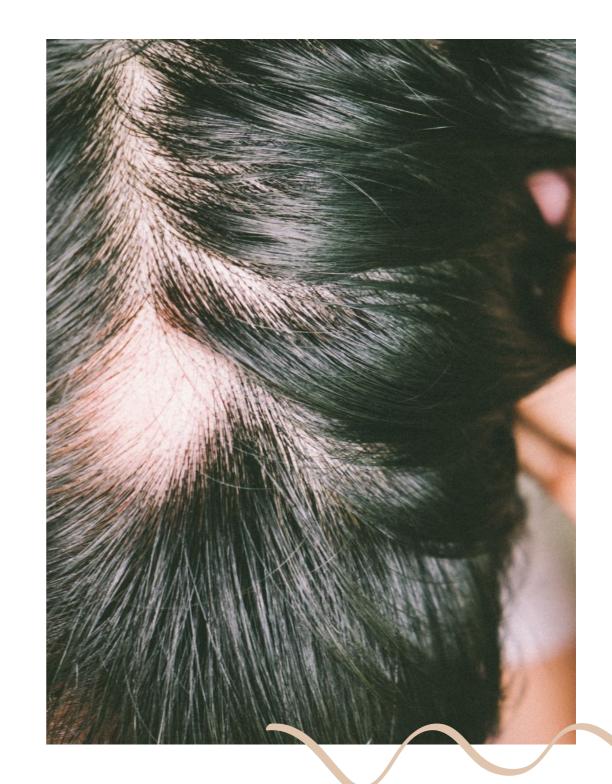
You haven't done anything wrong

Scalp cooling may not be the smooth process that we all hope it will be. Something we hear from patients is a concern that if they do lose hair, it's because they did something wrong - 'I followed all the rules, but I have still lost hair'.

It is so important to know that you didn't do anything wrong. You have not failed.

Sadly, for some people, no amount of following the rules or listening to all the guidance can ensure that scalp cooling will give you fantastic hair retention. This can be particularly hard if you are seeing other people with lots of hair who seem to find it easy.

Try to find comfort in the knowledge that you did everything that you could - you protected your hair follicles, and that regrowth will come. That you acted on what felt right for you. And that you are not alone. Reach out to the scalp cooling community – you are not the only one feeling this way.





Hair shedding

Tell me what I need to know

Shedding is often the most dreaded part of scalp cooling. Hair loss can be distressing, messy and tiring. When shedding first begins, it is commonly and mistakenly seen as a sign that scalp cooling isn't working - but it is important to know that shedding is an inevitable and completely normal part of the scalp cooling process.

Here's some information on what to expect and how to cope with hair shedding.

Shedding happens to everyone who scalp cools – even people who retain lots of hair will see some amount of shedding

It usually starts between 14 and 21 days after your first treatment, as the chemotherapy's effect on the follicles begins to show. If you haven't scalp cooled, this is where total hair loss would begin. Scalp cooling will protect your follicles, but it can't save every hair.

Shedding doesn't mean that scalp cooling isn't working

Shedding is scary, no matter how much you anticipate it happening. It is common to feel panic and think scalp cooling isn't going to work once your hair starts to fall out. Try to trust the process and remember that what you are experiencing is normal and not representative of the rest of your scalp cooling journey.

The shedding is likely to be heaviest early in your treatment

This can vary a little and depends on the drugs you are receiving, but for the majority, the shedding will be at its worst after your second and third treatments. For most people, after this, it can slow down, but you should expect some level of shedding throughout your treatment.

Shedding isn't the same for everyone – shedding varies a lot from person to person but is mostly influenced by the drug regimen you are receiving

Some drugs such as such as doxorubicin, epirubicin, or cyclophosphamide, will cause more hair loss than other drugs such as docetaxel or paclitaxel. Use the Outcomes Calculator to get a realistic idea of the amount of hair retention you could expect with your treatment plan.

Shedding isn't a result of having done something wrong

You can follow all the guidance to the letter, and you will still experience shedding. It is not a sign of failure or that you have done something wrong, just an inevitable part of the scalp cooling process.

It's important to remove shedding hair

You may feel that the last thing you want to do when your hair is shedding is to encourage those loose strands out, but it so important that you continue to brush your hair daily and wash your hair regularly enough to keep it manageable. This won't remove hair that wouldn't have fallen out anyway, but it can help to prevent knotting, tangling, and even matting.

Shedding will likely change if you swap drugs

If your regimen changes from one drug to another, there may be an initial increase in shedding. This is your hair follicles and body adjusting to the change in drug. It will likely happen 14 to 21 days after the first treatment with the new drug, but it can happen sooner too. Most of the time this increase is temporary.

Deal with shedding in a way that works for you

Dealing with heavy shedding can be difficult. Don't be afraid to tie your hair up loosely, wear a sleep cap at night, or even wear a hair net when you are at home to help catch those stray hairs.

Seeing hair in the shower or on your brush can also be tough. Ask for someone to help you if it feels easier. Some people have found heavy shedding so tough that they decide to cut their hair off but continue to scalp cool. This gives the benefit of faster regrowth but means the hair loss is no longer an issue. Whatever you find works for you, go with it.

Shedding and regrowth can happen at the same time

It's normal to see hair loss happening as new hair also starts to grow. The two processes can absolutely happen at the same time.

Don't forget that shedding is a healthy function of your body

It's easy to forget when you are deep in your treatment that shedding is a normal and healthy process. Everyone loses around 100 hairs a day as part of the hair growth cycle.

Post-treatment shedding is also normal

Unfortunately, your last chemotherapy treatment doesn't necessarily mean the end of shedding. It can take many weeks for the drugs to work their way out of your system, 8 to 12 weeks of elevated shedding after chemotherapy is normal. If shedding persists for longer than this, it may be worth speaking to your doctor as other factors can affect hair retention, including low haemoglobin levels and anemia.



Significant hair loss

Sadly, significant or extensive hair loss can happen for some patients who scalp cool. This is usually the result of a particularly harsh drug regimen. Unfortunately, there are no guarantees with scalp cooling.

Here are a few commonly asked questions from those that have experienced a lot of hair loss:



Should I stop scalp cooling?

Scalp cooling may not have given you the hair retention rates you would have hoped for, but it is worth noting that cooling your scalp during chemotherapy has been protecting your hair follicles. If you stop scalp cooling, that protection stops. This means that you will not see the long-term benefit of scalp cooling – faster hair regrowth.

Is it safe to continue with the cold cap if my scalp is exposed?

Yes, absolutely. But it is important that you cover any exposed areas of scalp to make the treatment as comfortable as possible. There are a few ways you can achieve this – if you have retained hair that is long enough you can arrange it over any exposed scalp. Alternatively, a disposable theatre/surgical cap will be thick enough to provide a barrier between your scalp and the inner cap, but not so thick that it stops the cooling effect.

I hate the way my hair looks now; can I shave my head?

Of course, if it would make you more comfortable there is no reason not to cut your hair. Just be mindful that you may benefit from a theatre/surgical cap worn underneath your inner cap.

I have lost most of the hair at my crown, why is this?

The crown is the area where scalp cooling has the most work to do because it is the hottest part of your scalp, and in some people, it just can't cool the scalp to the right temperature to prevent hair loss. We are working on ways to tackle this, and hope that in the future, this shouldn't be a problem for patients.

If you have high levels of hair retention everywhere other than your crown, this could be a sign that you have a cap that is too small. As the coolant from the system fills the cap, it will become tighter and if your cap is too small, it can rise and prevent proper contact with your scalp at your crown. Watch our 'How-To' videos for guidance on cap fitting and how to put the cap on properly, and if you're still concerned with the size of your cap, speak to your clinical team.

My hair loss is patchy, why is this?

As mentioned above, losing patches of hair at your crown is not uncommon, but you may see patches of hair loss in other areas of your scalp. Usually this is because the cap is not in full contact with your scalp. This might be due to the shape of your head (it's normal to have flat or recessed areas on your scalp), or it could be a problem with the way your cap has been put on. Watch our 'How-To' videos for information on how to get the best possible fit.

Could I have done anything to stop the hair loss?

In most circumstances, there isn't anything anyone could have done to prevent significant hair loss. If you were prepared for your treatment, got a great cap fit and put it on properly, there is nothing else that you could have done to change the outcome. Sadly, there are certain factors that are out of your control when it comes to hair retention – see more at coldcap.com/get-the-most-from-scalp-cooling

Hair regrowth with scalp cooling

Most people choose scalp cooling to try and retain their hair through chemotherapy, but increasingly we are seeing faster and healthier hair regrowth with scalp cooling become a key decision-making factor.

Tell me what I need to know

Some people facing challenging regimens now consider fast regrowth to be the most important part of scalp cooling, with any hair retention being a bonus.

As we know, retention rates with cold capping can vary a lot from drug to drug as well as from person to person - even those with the highest rates of hair retention see shedding, so faster regrowth is a true benefit to anyone who chooses to scalp cool.

For a long time, it was believed that scalp cooling resulted in faster regrowth, and now there are several clinical studies to confirm this.

A study conducted in Japan in 2019 called 'Efficacy of Scalp Cooling in Preventing and Recovering from Chemotherapy-Induced Alopecia in Breast Cancer Patients: The HOPE Study', concluded that scalp cooling resulted in faster recovery of hair volume within 12 weeks of chemotherapy, even in patients where scalp cooling failed to prevent chemotherapy-induced alopecia.

This was particularly important for the patients in the trial who received TC (docetaxel and cyclophosphamide), or AC (doxorubicin and cyclophosphamide), both of which are particularly challenging regimens for hair retention.

As you can see from the photos (below), not only are the hair retention rates higher for patients who scalp cooled, but the rate of hair regrowth is notably faster than the patients in the control group who did not scalp cool.







A study conducted in 2020 in India 'Randomized Control Trial of Scalp Cooling for the Prevention of Chemotherapy Induced Alopecia' concluded that scalp cooling patients saw significant hair regrowth at both 6 and 12 weeks post their final chemotherapy treatment.

At 6 weeks, 89% of the patients who had scalp cooled saw grade 0/1 alopecia (less than 50% or no noticeable hair loss), whereas the control group who didn't scalp cool saw 12% of patients with grade 0/1 alopecia. By week 12 this had increased to 100% of the scalp cooling group, and 60% of the control group.

As you can see from these study images (left), faster regrowth is important for those with good levels of hair retention, but even more important for those that see significant hair loss. Hair regrowth will happen naturally, but scalp cooling can help speed that process up, from a timescale of months to weeks.

It is also worth noting, that it is not uncommon for patients to see regrowth occurring before the end of their chemotherapy treatment with some drug regimens.

Finally, it is important to know that scalp cooling has been shown in studies to prevent persistent chemotherapyinduced alopecia (PCIA), which can occur in patients that receive high cumulative dosages of a taxane drug called docetaxel (Taxotere). While PCIA can be improved, it is a long-term side effect that can have a significant impact on a person's quality of life. The protection that scalp cooling provides to the follicle may not always be able to prevent short-term hair loss, but a study conducted in Spain in 2018 'Persistent major alopecia following adjuvant docetaxel for breast cancer: incidence, characteristics, and prevention with scalp cooling' showed that scalp cooling can ensure that long-term hair loss is not a problem that patients have to face. No patients in the study had grade 2 persistent alopecia (50% or more hair loss) and 0.8% of patient seeing grade 1 persistent alopecia (50% hair loss or less).

Commonly asked questions on regrowth

When will I start to see regrowth?

There is no fixed answer for this. Some people may see regrowth before the end of their chemotherapy treatment, but this is usually only with taxane drugs. For others it can take many weeks. As seen in the studies listed above, most patients will see regrowth by 12 weeks after their chemotherapy treatment is completed.

Will regrowth start before I finish chemotherapy?

It is possible, particularly if you are receiving a taxane drug (such as docetaxel or paclitaxel) and you are having more than 4 rounds. However, don't feel if you don't see regrowth before the end of treatment that scalp cooling has been a failure. It may take a little time, but the regrowth will happen.

It's been weeks since I finished chemotherapy, why haven't I seen regrowth yet?

This can be disappointing but try not to be disheartened. Seeing regrowth at 12 weeks is common - this can feel like forever but know that it will happen and try to be patient. Many people will search and search for regrowth and suddenly, it's there.

New hair is growing in but I'm still shedding, why is this?

It's completely normal for hair shedding and regrowth to happen at the same time. It is just the normal hair growth cycle happening. Some hair follicles have reached the end of their growth period while others are just starting.

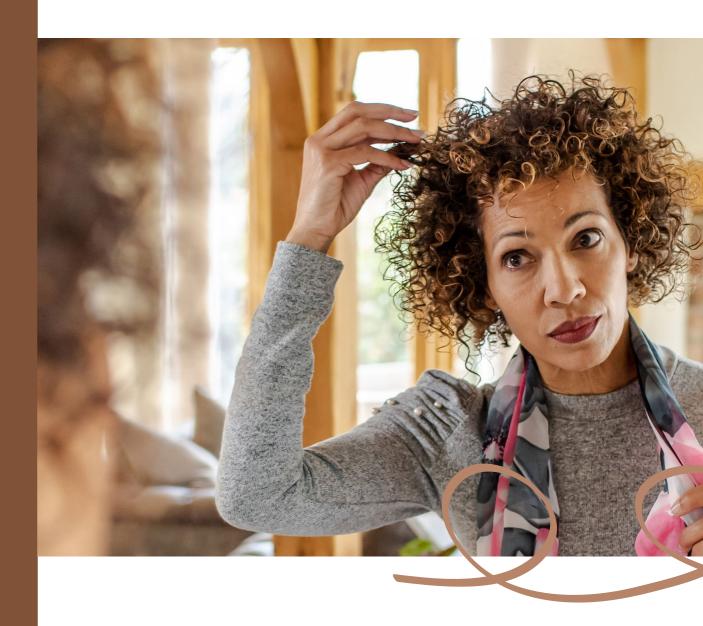
Why is my new hair growing in a different color and texture?

The texture of your hair is dictated by the shape of your hair follicle – which can be altered by chemotherapy. Straight hairs grow from round follicles, while wavy and curly hairs come from follicles with an elliptical or a flattened shape. Chemotherapy can change the shape of your follicles and many people see what are commonly called 'chemo curls'. Those with shorter hair often have a more pronounced texture, which can then become less obvious as the hair gets longer and heavier – you may start with ringlets and then end up with waves.

The same can also happen with the part of your follicle that provides pigment to the hair. Most often people will see grey regrowth, but it can change to a different color too. This may not be permanent, and after a while the color may return to what you had pre-chemotherapy.

I am so glad to see regrowth, but my hair is lots of different lengths and looks dreadful, what should I do?

This can be a tricky one. While it is tempting to act as soon as your chemotherapy is finished it can be worth waiting a while until you know what your regrowth will look like. Have a conversation with your hairdresser — they may have advice on how to manage the awkward stage without having to cut all your hair off. You may not end up with your haircut of dreams for a little while, but there is a lot that can be done if you can be patient. For example, it may be possible to create a transition short bob that will grow out smoothly rather than having to go for a full pixie cut.



Increased rates of hair regrowth are why we would always encourage patients to continue to scalp cool, even if they do see a lot of hair loss.

It can be hard to face significant hair loss despite using scalp cooling, but the impressive levels of hair regrowth can make that process feel worthwhile and that scalp cooling was still very much the right decision to make.

Further information on scalp cooling

06

Scalp cooling can be used by adult cancer patients receiving chemotherapy to treat solid tumor cancers such as, but not limited to, breast, ovarian, other gynecologic, lung and prostate cancers.

There is no evidence to show that scalp cooling is more or less effective for different genders, ethnicities or with different hair types.

As the manufacturer of a medical device, we are required to provide you with the following information. It has been written in a way that meets regulation, but it isn't always the easiest to understand. If you have a question on any of the information that you find below, speak with your clinical team for guidance.



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 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

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Contraindications

Contraindications describe circumstances or conditions in which a medical device, drug or treatment should not be used.

Scalp cooling is contraindicated in pediatric patients.

Scalp cooling is also 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 haematological 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 later
- 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

Side effects

A side effect is a secondary or unintended effect of a drug or medical treatment, which are often undesirable.

Known side effects associated with scalp cooling include:

- Chills
- Dizziness
- Headache
- Nausea
- Pruritus (severe itching)
- Sinus pain

- Skin tissue disorders
- Skin ulceration
- Paraesthesia (an abnormal sensation such as tingling, tickling, pricking, numbness, or burning of the skin - a "pins and needles" feeling)

Safety

The following information outlines research showing that scalp cooling is a safe treatment.

The only known potential long-term side effect of scalp cooling is also the most controversial one; this is that scalp cooling when used on women receiving chemotherapy for breast cancer could lead to an increased incidence of scalp metastases. (This is because the same mechanisms that restrict the effectiveness of the chemotherapeutic agent against hair roots or follicle cells in the scalp can also restrict the effectiveness of the chemotherapeutic agent against cancerous tissue in the scalp.)

The natural incidence of scalp metastases in patients with breast cancer is approximately 1 in 4000. This incidence seems to be about the same in patients who receive scalp cooling and those who don't.

There is no clinical evidence that cooling the scalp during adjuvant and palliative chemotherapy treatment increases the risk of developing scalp metastases. The issue remains a theory or possibility, but it has not been proven. The Paxman Scalp Cooling System is the leading product found to minimize the risk of hair loss during chemotherapy in women with breast cancer. Your healthcare professionals can advise you if scalp cooling is likely to be successful with your chemotherapy treatment, or whether any other treatments, or the use of a wig, scarf, or headcover, may be more appropriate.

Scalp cooling has also been proven to have no negative effect on survival rates.

For more information on the research done into the safety of scalp cooling please visit paxmanscalpcooling.com/efficacy-safety

coldcap.com

facebook.com/groups/paxmanscalpcooling

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