Transcript Details

This is a transcript of a continuing medical education (CME) activity. Additional media formats for the activity and full activity details (including sponsor and supporter, disclosures, and instructions for claiming credit) are available by visiting:
https://reachmd.com/programs/cme/clinical-treatment-challenges-of-seborrheic-keratosis-still-stuck-on-the-surface-of-care/10704/

Released: 04/01/2019
Valid until: 04/01/2020
Time needed to complete: 1 hour

ReachMD
www.reachmd.com
info@reachmd.com
(866) 423-7849

Clinical & Treatment Challenges of Seborrheic Keratosis: Still Stuck on the Surface of Care

Announcer: This is CME on ReachMD. The following activity titled “Clinical and Treatment Challenges of Seborrheic Keratosis” is jointly provided by Postgraduate Institute for Medicine and HealthMattersCME and is supported by an independent educational grant from Aclaris Therapeutics.

Prior to beginning, please be sure to review the faculty information and disclosure statements, as well as the Learning Objectives.

We begin this activity with a presentation on Seborrheic Keratosis prevalence, clinical features, subtypes and differential diagnosis by Dr. Glynis Ablon.

Dr. Ablon: So I am going to assume that every single person here has treated at least one seborrheic keratoses in their career, yes? We see these on a regular basis. This is probably the most common thing we as dermatologists see in our practice and we know that it is something that becomes more common with age. In Australia, the numbers were between 15-25 years of age that 12% of individuals actually had seborrheic keratoses. Once you hit 50, 100% of those individuals have seborrheic keratosis, in Australia that is. In the U.S., there are 83 million Americans that have seborrheic keratoses. Over the age of 65, about 90% of individuals in the U.S. have seborrheic keratoses and that’s one or more of those lesions. And again, many of us have multiple lesions that are present all over the body.

We don’t exactly know the exact etiology for seborrheic keratoses. They are frequently appearing in sun exposed areas but as we all know, they can appear anywhere on the body; we see them in areas that are hidden from the sun. We know that there are potential etiologic factors that include the papilloma virus, the abnormal skin proliferation, as well as germline mutations and that can increase susceptibility in families that have keratoses more commonly seen.

This I think is interesting – more than 80% of seborrheic keratoses actually have one oncogenic gene mutation and 45% of them have two or more oncogenic gene mutations and so I think that’s important because even though we think of seborrheic keratoses as benign lesions, the question becomes is there a potential for something to happen or something to change? We know that again there are UV mutations associated and this again suggests that these lesions are potentially at least partially associated with chronic sun damage. But what’s also interesting is that these mutations, you get an actual gene coding of the tyrosine kinase receptor. It’s found in 40% of the hyperkeratotic lesions or seborrheic keratoses, 40% of acanthotic seborrheic keratoses and 85% of the reticulated keratoses and so again this is something that we need to keep in mind when we’re evaluating these lesions.

Most people find them asymptomatic; however, we do see in our practice and in most practices that people will come in complaining that they itch, that they’re irritated, that they catch on their clothing, that they are bothersome and they do want them treated. Typical lesions will appear to be light brown; they can be dark brown as well and I do see patients that come in with lesions that are the same color as their skin type, so a tan or a light color, so again they can be different colors. Most of the time we can look at them and clinically say this is a seborrheic keratosis and we feel very confident with that diagnosis. But, there are lesions that can actually mimic other kinds of skin tumors, including things like melanoma and that is probably the most common reason some outside physicians that are non-core physicians that will send me a patient with a lesion and it will say rule out melanoma when it’s actually a seborrheic keratosis.

They’ve listed on here the typical gross appearance and again most of us understand and see this regularly. They can range from small lesions – 0.2 cm in size – up to 3 cm and sometimes even larger than that. When we look at a keratosis, we are expecting to see

something with that warty, hyperkeratotic, stuck-on appearance. Some people will call them barnacles, some people will call them lesions. Again, I call them wisdom spots because I think as we all get wiser, we get them and they can again be any color from tan, brown or black. The thickness of them can vary and again some of them can resemble melanomas. When you're seeing the horn cysts, those classic horn cysts or the black or white pearly cysts on the surface, that typically is a good sign that you are dealing with a seborrheic keratosis and not something of concern.

Differential diagnosis: I've had a number of gentlemen and women come in with lesions in the groin area and my differential does include the condyloma and I do think in that area, frequently they can mimic a seborrheic keratosis, I will biopsy those and they have come back condyloma and of course the treatment is different than that of an SK because you don't have to treat the SK but you do want to treat the condyloma acuminata.

Other things, again, melanocytic nevi, verruca vulgaris – sometimes they can look so similar that it's hard to tell but the things that we worry about even more are the premalignant or malignant lesions, especially when a keratosis is irritated or scratched at or picked at, that's when you really have to wonder whether or not we're dealing with a Bowen's or a squamous cell carcinoma or again if these lesions are in the adenoid family and look potentially like a melanoma so that's where we do want to make sure that a biopsy is performed. And this study actually showed – they did a retrospective study of 813 specimens and even though in that situation, less than 1% actually were melanomas. I do think it's important that we realize you don't want that 0.66%; you don't want to have that one case or two cases or five cases that end up being melanoma that you missed. Biopsy of course if you are not sure.

Again, lesions can be irritated, they can turn a reddish/brownish color because of the irritation, they can grow, itch, bleed. If I'm concerned about it and I'm not sure but I'm not thinking this is something dangerous, sometimes we will go ahead and clean it, put some antibiotic ointment on it or some Vaseline or some Aquaphor, cover it, let it heal for a few weeks and reevaluate when the lesion has healed completely to determine whether or not they do need it removed. But again, if you're concerned, an immediate biopsy is an option.

Do remember, as we're taught in medical school and residency the sign of Leser-Trelat. If you have someone that comes in and suddenly has a number of these keratoses appearing, especially on the back or on the torso, that sudden onset of numerous keratoses is something to be concerned about and that is where we do look for some kind of paraneoplastic dermatosis, some kind of internal malignancy. We don't want to miss that. You can also get that pseudo-sign of Leser-Trelat and that is something where certain medications can cause it.

So the interesting part again is we think of seborrheic keratoses as benign but you can have malignant tumors that actually develop next to, within, in the center of these seborrheic keratoses and the question is, are they somehow related to the seborrheic keratoses? Or are they just perhaps by accident – they're two different tumors that have collided together and they're completely different lesions even though they're in the exact same spot? Yes, seborrheic keratosis transformation into something malignant is rare but I think it's important to understand that they have found squamous cell in situ, basal cells, adenocarcinomas and melanomas within seborrheic keratoses so it's an important thing to be aware of and again if there's any question, to remove.

Pigmented seborrheic keratoses versus melanoma – again, we know what the classic look is but sometimes it can be different and sometimes you don't see the classic signs and you don't see the horn cysts and it's not warty and it's not thickened and so if it's a very early lesion, it can be suspicious so if you're not sure, you want to do a biopsy and you don't want to miss something like that. There are again several seborrheic keratoses subtypes that can mimic these melanomas or even pigmented basal cell carcinomas.

How many of you use dermoscopy for keratoses, seborrheic keratoses? Not everyone does dermoscopy. I do use it in my practice regularly, it is an adjunct to the visual examination and it can have a variety of dermascopic features and so again, if you're suspicious, especially if the dermoscopy is leaning you towards something more suspicious, a biopsy is warranted.

Here are some classic things that we look for when you're looking at dermatoscopes – with seborrheic keratoses, we're looking for those fissures and ridges, which typically can be seen with the naked eye but not always. You're looking for the hairpin vessels; milia-like cysts again are the typical classic things that we see without the dermoscopy but if you can't see them with the clinical eye and you can see them under the dermoscopy and you can see in this picture here, you can see really closely those little comedo-like openings and again those are more classic for the seborrheic keratoses. But important to understand that you can still see some little comedo-like cysts with melanocytic nevi, not necessarily melanomas, but you can see the vascular patterns. Ulcerations, crust, those are things that we worry about and tend to lead me towards doing a biopsy of the lesions.

So surgical versus medical – there are actually no guidelines for the treatment of seborrheic keratoses. I teach over at UCLA and I do a lot at the VA and frequently patients will say that they want them treated. Cryotherapy can be used and patients do oftentimes like these treated because they're annoying, they can itch, they bother them, they don't like the look of them as well. So cryotherapy with the liquid

nitrogen, electrocautery, curettage, shave biopsies, excisions, ablative lasers, dermabrasions are all different varieties of treatments that can be done to eradicate these seborrheic keratoses. The most common are the cryosurgery and the electrocautery for treatment of seborrheic keratoses.

I think the biggest thing to understand is when you're using cryotherapy, which is why I don't love it as a first-line treatment, pigmentation is a big deal and if you freeze too hard, you do liquid nitrogen for too long of a period of time, these patients have white marks all over their body and you see a lot, especially over at the VA where I am a lot, patients that come in with multiple white spots all over their body that have turned into permanent lesions. However, they prefer those over the thickened, itchy keratoses themselves. So again, postinflammatory hyperpigmentation, hypopigmentation can be seen with all of these procedures. The hypopigmentation is most commonly seen with the cryotherapy and more commonly seen in darker skin types. So again, be aware when you're doing something, talk with your patient, make sure they understand the risks of the treatment that you're offering and understand the complications that can go along with that and then they get to make an educated choice of what they want to do. When you're dealing with freezing, doing the cryotherapy, frequently it can take more than one session, which is actually a good thing because if you freeze too hard, again, that's where you can scar or cause pigmentation alteration.

Cryotherapy versus the electrocautery – how many of you do cryotherapy in the office for seborrheic keratoses? And how many do electrocautery in your office? I will paint the lesions if I'm going to do electrodesiccation. I will paint the lesions with some Drysol first so that I actually soften the lesion before I do any kind of curettage or desiccation following that. Again, when you're doing these procedures, you can get pain, you can have erythema, of course crusting, bleeding, edema and then of course a blister formation if you're using the cryotherapy. All side effects or complications that you need to be making your patients aware of.

Efficacy – they did a study, they showed that patients preferred cryotherapy. Even long-term, after 12 months, the percentages still preferred the cryotherapy. I find, though, that with my practice, I can use the electrocautery after I do some curetting. I will use that and I find that my patients have one treatment as opposed to multiple sessions and I find it works a little bit better in my hands and patients do really well with that. Again, both methods are acceptable for the treatment of these lesions.

You can also do ablative lasers and I'm usually doing it for things, not just for a keratosis but if they need it for other lesions, especially on the face, that's something I can offer and treat kind of everything at the same time. Again, you can do Er:YAG laser, which is what I use in my practice and again 100% cleared with one treatment versus 68% in the cryotherapy group. Hyperpigmentation is not as common, again, depending on your skin type but you can get erythema and that can be prolonged with Er:YAG resurfacing.

These are my patients – my pictures, my patients. This is a patient before and immediately after we did some electrodesiccation and curettage and she'll be healed in about five days. And then this is a patient of mine who had a mixture of seborrheic keratoses as well as some actinic keratoses and this was three months after ablative laser. The patient was very happy and had good results with that.

So when we are deciding what to do, make educated choices, discuss with your patient what your options are, how you can treat the lesions and also make sure that what you're dealing with isn't something that should be biopsied. So evaluating the lesion, looking at it clinically, considering dermoscopy if you're not sure and deciding what to proceed with. Again, this is the most common lesion that we see and we know that there is some relation with exposure, UV exposure and genetic mutations and oncogenic genes and so while they're benign, patients really do want these treated. We always worry about malignant conditions and if you're concerned do a biopsy and be aware that they can coexist with other malignant tumors.

Announcer: Dr. Brian Berman speaks to us on "New and Emerging Topical Treatments" in the second presentation of this CME activity.

Dr. Berman: Good evening. I've been asked to focus on new and emerging treatments for seborrheic keratosis. I'm going to start off with the newer ones that have the least amount of data to support and then build up to the more recent FDA approved treatment for seborrheic keratosis. So there's potassium dobesilate 5% cream and it inhibits the fibroblast growth factor receptor three that Glynis mentioned is upregulated in about half or maybe even the majority of seborrheic keratoses. Well, this would inhibit this receptor and therefore decrease the formation of seborrheic keratosis. Well, that's all in theory; this was just a single case report of topical potassium dobesilate and it was demonstrated to have efficacy for a facial seborrheic keratosis within six months and it was maintained as efficacious for up to one year of the patient's application. The good news is there were no adverse events noted in this case report. But it's attractive because it does have a mechanistic basis for it.

I think we're all familiar with the non-steroidal antiinflammatory drug diclofenac gel 3%, which is FDA approved for the treatment of actinic keratoses and it showed some promise, again, unfortunately just in a single case report of a 73-year-old man with a seborrheic keratosis on his nose. It disappeared within 30 days of twice daily using the diclofenac gel.

Tazarotene 0.1% cream was applied twice daily and it produced improvement in about half of the patients and it took 16 weeks but it was more effective than daily applications of its comparators in the same study – calcipotriene ointment as well as imiquimod 5%

cream, neither of which had any clinical improvement. So there is some potential for tazarotene but again, only about half the patients showed improvement.

Then there's BL 5010, which is a combination of trichloroacetic acid and formic acid, so it's a topical formulation and it's applied with a pen device to the target seborrheic keratosis lesions. This is a formal study of 60 patients. It was a phase I/II trial and one application using the pen device with the BL 5010 eradicated over 90% of seborrheic keratoses within two weeks, so there's some potential for the future.

How about topical vitamin D? Well, it has been studied but unfortunately has met with limited success as an option for eradicating seborrheic keratoses. A larger study – 116 cases now of topical vitamin D, was able to eliminate greater than 80% of the seborrheic keratoses. That's the good news, but only in about 30% of patients. The other bad news was of those seb kers that actually responded to the vitamin D topically applied, the majority tended to recur over time once the vitamin D was stopped being used. And finally, two Akt protein kinase B inhibitors have been studied in early trials in seborrheic keratoses, one of which the seborrheic keratoses responded completely and disappeared so that's another future possibility.

But now, let's move on to the only FDA approved topical treatment for seborrheic keratoses and that's 40% hydrogen peroxide. To get a drug approved through the FDA in the derm division, usually it requires two pivotal phase III randomized, double-blind, vehicle-controlled trials and that was the case for the 40% hydrogen peroxide solution, which compared the hydrogen peroxide treatment to placebo in almost a thousand patients, 937 adults. Each patient had four raised typical seborrheic keratoses. One of those seborrheic keratoses had to be on the face. One of those seborrheic keratoses had to be either on the extremities or on the trunk but the patients had to have four. The lesions had to be less than 2 mm thick but it had to be raised in order to get into the study and the greatest diameter had to be between 0.5 cm and 1.5 cm in size. Those are the vast majority of seborrheic keratoses we do see.

The treatment via the vehicle or the 40% hydrogen peroxide was repeated after 21 days, so there were two treatments, on day one and on day 22. It was applied in a circular motion on each of the seborrheic keratoses for 20 seconds using a pen-like device. Each lesion then was treated a total of four times at that treatment and there was about a minute interval between those four treatments. Now that sounds a little difficult but it really isn't because if you treat one, then you move to the second and then you move to the third, do it four times, then to the fourth one four times, then you come back to the original one in a circular motion for 20 seconds, that was about a minute to go around the clock.

Okay, so this was a study, as I said, of almost a thousand patients. There were two studies. The patients were randomized to either getting the hydrogen peroxide or getting the vehicle. The patients received that treatment on day one; the treatment was then repeated 21 days later on day two, and then the endpoint of the study was at day 106. What were the criteria for efficacy? Well, it was based on something called a physician's lesion assessment, the PLA. And the PLA grade ranged from 0 all the way to 3. Let's go over what these were. Zero meant that the seborrheic keratosis was completely gone. I should mention that if there was any blush of erythema, that was not counted as presence of a seborrheic keratosis but if one could see any residual seborrheic keratosis, it couldn't be 0. Then there's grade 1 where you can see some residual of the seborrheic keratosis but you can't feel it. It's completely flat. Grade 2, less than 1 mm raised but it was raised. And then grade 3 on the PLA was clearly visible seborrheic keratosis with a thickness greater than 1 mm.
In an overview of the study results with respect to efficacy, 51.3% of the seborrheic keratosis lesions that were treated with the 40% hydrogen peroxide solution were determined to be either clear or near clear – that would be a PLA of 0 or 1 – compared to only 7% treated with the placebo and the treatment with the 40% hydrogen peroxide cleared or almost cleared 65% of the facial lesions compared to 10% for the placebo. And in fact, with post hoc data, showed that the facial seborrheic keratoses were the most responsive to the treatment with hydrogen peroxide.

Let's look at what the FDA wanted with respect to efficacy before they would approve this drug. They made it very difficult. The primary endpoint was that all four of the lesions that the patient had had to be completely clear. That's four out of four had to have a PLA of 0. If one of them had a PLA of 1 – almost clear – that patient completely failed. So the FDA focused on the whole patient with all four lesions rather than purely the number of lesions that responded. So what percent of patients actually had complete clearance of every one of their seborrheic keratoses that were treated? It was about 6%. None of the vehicle patients had any response. How about a secondary endpoint of three out of the four lesions that the patient had had to be completely clear? Now it was about 16-18% of the patients who were treated with the hydrogen peroxide achieved that endpoint. Again, those that were treated with the vehicle failed completely; none of them fulfilled that criteria.

Now let's move on from looking at the patients, but let's look at the actual lesions that had a score of PLA of 0 – that means they completely cleared – and about 30% of the lesions per patient completely cleared and about 50% of the lesions either completely cleared or almost cleared with the hydrogen peroxide. Well, how about the safety of using the hydrogen peroxide solution? Now if you look at this graph, you'll see there's a little bump at day eight and day 29. Day eight and day 29 is one week after the actual treatments,

so with respect to redness and erythema, there was a peak on the day of the treatment but you can see that the erythema drops off after… in the case of day 22 or in the case of day 50 and 78, it drops off over time but it peaks on the day of treatment. The same thing for edema – there's a peak on the day of treatment but then pretty much gone even by day eight or one week after the second treatment, day 29. In response to the treatment, there's a peak of scaling on day eight and day 29, about a week after the original treatments but they also disappear; the scaling also disappears with time. And the same thing for crusting, which makes sense. You treat it on day one; a week later, day eight, you have some crusting, the same thing for day 22 treatment. You don't have crusting on that day because the crusting from the original treatment is all gone and then on day 29 you have a little more crusting.

What does it look like in a patient? Here's a patient with multiple seborrheic keratoses on the neck, jaw line and also in the preauricular area. This is on day 22 after the end of the first treatment but before the patient got a second treatment. Some of them are already gone, gets a second treatment and on day 106, this patient, all her lesions have responded to the hydrogen peroxide solution.

Now Glynis mentioned about hypopigmentation and that seborrheic keratoses do occur in patients of color and one of our standards of care is liquid nitrogen. What's the problem with liquid nitrogen? It is toxic to melanocytes and may induce hypopigmentation in our pigmented patients. Now this is an interesting type of study where they excised skin from patients of color and put it into tissue culture and then Adam Friedman the principle investigator, treated the skin in tissue culture with liquid nitrogen or the 40% hydrogen peroxide and then measured the survival rate of the melanocytes and whether the melanocytes underwent apoptosis, natural program cell death from these two treatments and then compared them. And I won't go into the details of all those graphs but it turned out that treatment of the skin in vitro with hydrogen peroxide 40% caused less lethality and was less cytotoxic than cryosurgery – liquid nitrogen exposure. There was greater sparing of the melanocytes in all three of the assessments, suggesting that maybe clinically, using the hydrogen peroxide may ultimately result in less hypopigmentation because of the melanocytes surviving at a greater rate than if you treat with liquid nitrogen.

So in summary, there are a number of new and emerging topical agents for the treatment of seborrheic keratoses. The 40% hydrogen peroxide solution is the only FDA approved topical agent for the treatment of raised seborrheic keratoses based on the studies that we just went over, demonstrating both its efficacy, safety and tolerability.

Announcer: In this final presentation, Program Chair Dr. Mark Nestor speaks to us about Coding Regulations and Documentation, Economic Hurdles & Patient Education.

Nestor: Thank you. Thank you Brian. Well, let's talk about some really practical aspects of coding regulations, documentation, economic hurdles and patient education. So let's talk about the issue of non-covered procedures. Patients understand that insurance does not cover everything. They clearly understand this for cosmetic procedures such as toxins, fillers or devices but procedures that are not covered also include non-suspicious and non-inflamed seborrheic keratosis and non-reimbursed procedures such as clinically covered conditions including lasers. And dermatologists have the knowledge base but proper education and communication are really critical for these self-pay, non-covered procedures.

Now there's a definition of non-covered procedures that are not reimbursed by insurance companies or any insurance companies or given insurance companies. Certainly cosmetic falls into this; it's usually not covered under certain circumstances like toxins and certainly for headaches, toxins can be covered as well as hyperhidrosis. Not recognized by insurance such as lasers for acne or nails, and removal that is not medically necessary to treat that patients find ugly. Also, preventative treatments usually, such as laser, photodynamic therapy for Photodamage are non-covered procedures.

Now according to Medicare, medically necessary is defined as healthcare services or supplies needed to prevent, diagnose or treat an illness, injury or condition/disease or symptoms that they meet accepted standards of medicine or medically reasonable and necessary to the overall diagnosis or treatment of the beneficiary's condition or illness or to improve the function of a malformed body member. It's new, I don't like it, it's ugly, it itches or it gets caught on my chains are not reasons for medical necessity in the absence of clinical findings. So the definition also includes the removal of benign lesions that may fall under a category of medically necessary such as the removal of an inflamed cyst on the back. So the idea here is what is not medically necessary versus what is medically necessary. The procedure used for an excision has CPT and ICD-9 codes and for some cases you need a written advanced beneficiary notice, which must be given to the patients and in that case a charge Medicare allowable.

So cosmetic procedures are certainly not covered and cosmetic surgery and expenses are certainly within that. And cosmetic surgery includes any surgical procedure directed at improving the beneficiary's appearance and the exception are therapeutic purposes that may be coincidental to improve their appearances. So cosmetic is based on the intent to look better, including the removal of unsightly spots such as seborrheic keratoses. Certainly procedures to enhance appearances is cosmetic; the intent is the crucial factor. Fillers, toxins or laser resurfacing to look better, removal of these spots and the patient does not want them there. How many times a patient comes in and says yes, I know, I know this is nothing but I don't want it there. I don't like it; it just doesn't look good. I think we have that every day

from our patients. And the way we use this is we use the CPT code and then ICD-9 is Z41… ICD-10 of Z41.1.

Now it's important to understand that non-medically necessary and cosmetic has concerns because it is insurance fraud to improperly document to get coverage for a non-medically necessary or cosmetic procedure. And we have to counsel patients to tell them that they do not have to treat these lesions. Tell the patients you can remove the lesions but the procedure is cosmetic; it's to make them look better and not covered and that they are responsible for the charges. They understand insurance doesn't cover everything. Have them sign a waiver and a consent as well as a form to which they agree to the fee in advance. Document it as a cosmetic removal or a destruction and as I said, use Z41.1 and a meaningless A code and don't submit it to insurance.

So when a treatment of SK is medically necessary and when is it covered for a diagnosis or treatment? Certainly, as Dr. Ablon talked about, when it's suspicious for a malignancy, you can do a biopsy and document the biopsy was performed for a neoplasm of undetermined origin and you can use a code, and these are new codes now, like 11102, a shave biopsy code and the ICD-10 is D48.5, neoplasm of undetermined origin. So if it's significantly inflamed, red, crusted, bleeding, edematous and symptomatic, not just symptomatic in the absence of findings and that's important. Patients often come in and say I got all these spots on my back and they all itch so I want them off. The destruction of benign lesions or shave excision in this case for individual spots that are truly clinically inflamed, it can be multiple lesions, the code is either 17110 for destruction if you're doing to use liquid nitrogen, 11300-13 if you're going to do shave removals and at that point you're going to do L82.0, which is an inflamed seborrheic keratosis.

So treatment of SK that's not medically necessary but covered under certain instances such as a large, non-inflamed one on the back, may be associated with skin irritation, document that it's clinically benign and non-inflamed and not necessary, use destruction or shave removal codes and again, ICD-10 of L82.1 and charge the Medicare allowable in this case and you may want to do an ABM and unless the patient asks, you don't have to submit. Treatment of SK that's not medically necessary, not covered, non-inflamed, the patient doesn't want it there, etc., that's self-pay and the patient does not have to submit to insurance and they should sign a waiver.

Now, how do you discuss this with patients? And I think this is important because this has to do with patient education and this is really crucial for us to do. And the way I discuss this is to say this is a normal, benign spot and nothing needs to be done. Also, no insurance coverage, for normal, benign spots. And then I say we can take this off cosmetically; we do it the best way for appearance if you would like. The cost is 'X', $200, etc., we can't guarantee that it will not come back. There are a number of covered treatments for SKs but we also offer laser and other covered treatments that are not covered by yours or any other insurance and if I'm going to do photo rejuvenation for instance, I'll say the cost is 'X' amount for a series of treatments. Now, I will always say that we cannot guarantee results but in general, patients have improvement.

So, non-medically necessary SKs are certainly cosmetic if the patient does not like the way they appear and does not like the fact that they're present. Document specifically that nothing needs to be done, they don't need to be removed. Similar documentation is also done for laser treatments and other treatments. Non-cosmetic procedures, patients should sign a waiver, as I said. Always photograph these pre- and post- and most medical EMR/EHR systems make this easy. You give the risks and benefits and have the patients sign a consent and you should say it may not improve and you're not giving any guarantees and detail a procedure note.

This is our waiver agreement and it clarifies our office policy on non-covered procedures and that the patient doesn't need to have anything done, they understand this, and this includes moles, skin tags, seborrheic keratoses and other clinically benign lesions that patients feel are ugly – age related spots, laser treatments for things like acne or nails. Since these procedures are not covered, you have options including doing nothing and this is really key to this waiver procedure. And even though it's not medically necessary, this is important because if I'm going to shave four cosmetic seborrheic keratoses off, I still send it in to pathology because as Dr. Ablon talked about, I can always be fooled and if I'm going to cut something off, I will send it into pathology. And charge for pathology may be billed to your insurance or in other cases they may be responsible for it.

So at the end it says it's important that they understand the choices so there's no misunderstanding. The waiver is signed and we put down the price and the cost of the procedure and the patient signs this so there is absolutely no misunderstanding. And this has come in handy because I have had patients afterwards, weeks later who said I'm telling my credit card not to pay because I've decided it's not a good thing. And if you read here, it says I will be responsible. All we do is send the credit card a copy of this and we have never lost for the credit card to pay to us.

In addition, you need a consent. So in this case, it's a consent either for the destruction or removal of benign lesions and here it says they authorize me or my staff to do this. They consent for the diagnosis of a biopsy in this case. I understand the skin lesion is not cancerous, does not have to be destroyed or removed, it's not medically necessary and it's not covered by insurance. I understand the risks and benefits are all here, I understand it's not medically necessary. We have in Florida that it has to be regulated by 64B8-9.009, which is the standard of care, and the patient signs this and we have it in the documentation, the consent, which is important.

You also need to do a procedure note and the procedure note should be in the chart and in this case for non-covered service for a seborrheic keratosis, the patient was counseled about seborrheic keratoses, which are benign lesions that do not need to be removed. The patient wants a spot removed for cosmetic reasons, I give them all the risks and benefits of the different treatments. We talked about what's necessary in this and this is in the chart and the patient will call us for any evidence of increased redness or infection. This is part of the chart.

So the important thing to understand is that we have options in dermatology. Our patients come in not only for conditions that we can treat to make them healthier but also because they don't like things on their skin and we have the ability to charge patients for this and we have the ability to treat and have patients improve their appearance. In order to do this, patients must learn to be compliant, effective and efficient and remember the fact that we can tell patients so to speak that we have, through a conversation with them, options for them to treat seborrheic keratoses. They must understand the difference between medically necessary and non-medically necessary procedures. Educated patients are really happy to pay out of pocket; they understand. And we have to understand all the necessary documentation principles for our own benefit as well as for the patient's benefit.

So, I thank you. We have time now for questions and answers and I think that this can come from the audience. We have cards for this, if you have questions across the board for any of us. Yes, we have one up here. I need… we need to have you talk into the microphone up here. There you go. Thank you.

Participant: The pen, how many treatments can you do with the same pen?

Dr. Nestor: So the hydrogen peroxide therapy that Dr. Berman talked about, how many lesions? The issue is it depends on how big the lesions are. Our experience is anywhere from about six lesions to ten plus, depending upon the size of the lesion with one applicator.

Participant: Can you reuse it for another patient? Or you have to throw it out?

Dr. Nestor: You cannot reuse it for another patient.

Participant: Thank you.

Dr. Nestor: You're quite welcome. It looks like we have another question. Where do you get the 3% diclofenac? I guess that's for Dr. Berman.

Dr. Berman: Well, that's the Solaraze but again, that's off FDA labeling but… and you may have difficulty getting it because you're not treating an actinic keratosis for which it's actually approved. But it does exist, the 3%; it's called Solaraze.

Dr. Nestor: Okay, the next question is, if a biopsy of a suspected lesion happened to be a melanoma, would you reimburse the patient if they signed a waiver? The answer is yes, that's part of the waiver. So what we tell patients, if we send it in and it happens to be something, then we go back and then we will put this in as a biopsy for the patient, refund their cosmetic money if we're doing a shave removal. So the answer is absolutely, yes.

Participant: I have a 100% cosmetic practice, have no insurance plans. If I see somebody that I'm questioning could possibly be some sort of a malignancy, I do refer those to the dermatologist. Is it necessary for me to have the patient complete the non-medically necessary paperwork since I don't have any insurance plans anyways?

Dr. Nestor: So you're saying for the treatment of the lesion in your office, the question was do you have to have… so the answer is I would say yes and even if you don't participate in any insurance plans, it's a back-up for you to have something signed so the patient has absolutely no misunderstanding of not only what you're doing but the cost because I have a very big cosmetic practice, we do a lot of toxins, etc., and obviously patients know that this is not covered by insurance but I still have them sign that waiver all the time because it is a bond between us. The patient understands that they're paying today, the exact cost, and I think for any procedures we do cosmetically, it's a very, very big benefit for that communication. Other questions?

Participant: Is there any way to define the metered dose of what the patients are actually getting with each application?

Dr. Nestor: So Dr. Berman, would you like to answer that question? The question was can you define the metered dose. We did a demonstration of this product of the 40% hydrogen peroxide here. Once you get comfortable with it, you see by the pressure you're using with this pen-like device that you really do get a fairly reasonable metered dose. You go back, as Dr. Berman was explaining, to treat it a number of times. I'm also not clear that it's absolutely critical to have an exact amount and since the seborrheic keratoses are also different sizes, the idea is to fully treat that size lesion so I'm not sure the metered dose is applicable here because they're different sizes. Any other comments?

Dr. Berman: No, and also as a rule of thumb, once you're seeing the lesion completely whitening, then you know you've achieved the

right dosing.

Dr. Nestor: Yes. Thank you. So, I think in summary, I thank you all for your participation and this wonderful learning experience. I thank Dr. Berman and Dr. Ablon for their contributions for this. I think it's been a very worthwhile endeavor to understand a lot more in depth about seborrheic keratoses, about the etiology, about the possibilities of the different aspects to treatment, about the new innovations in treatment with 40% hydrogen peroxide and finally about really the conversation we have to have with our patients and understanding when things are covered and not covered, how we document. So thank you so much for your attention.

Announcer: This CME activity was jointly provided by Postgraduate Institute for Medicine and HealthMattersCME.

To receive your free CME credit please be sure to complete the posttest and evaluation by visiting ReachMD.com/CME.

Thank you for joining us.