Lymphedema Workgroup Report

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Commissioner

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Legislative History

Currently, required coverage for lymphedema treatment, equipment and supplies is limited to the coverage provided under §15-815(c)(2) of the Insurance Article, which is coverage for physical complications of all stages of mastectomy, including lymphedemas. The Coverage for Lymphedema Diagnosis, Evaluation and Treatment bill was introduced as HB 113 during the 2016 Maryland General Assembly Session and again as HB 667 during the 2017 session. In both years, the bill was given an unfavorable report by the House Health and Government Operations Committee ("HGO") and was withdrawn by the plan sponsor. As proposed, this bill would provide a new mandated benefit standard requiring an insurer, nonprofit health service plan, or health maintenance organization that provides hospital, medical, or surgical benefits to provide coverage for the medically necessary diagnosis, evaluation, and treatment of lymphedema including equipment, supplies, complex decongestive therapy, gradient compression garments, and self-management training and education.

Maryland Healthcare Commission Report[1]

As required by §15-1501, Insurance Article, Annotated Code of Maryland, the Maryland Healthcare Commission ("HCC") must evaluate the impact of proposed mandated benefits. In 2016, the Maryland Healthcare Commission contracted NovaRest, Inc. ("NovaRest"), an actuarial consulting firm, to assess the impact of the previously proposed mandates and issued a report to the General Assembly in January 2017. NovaRest surveyed the six largest commercial health insurance carriers in Maryland to determine the degree to which they provide coverage for the services described under HB 113/HB 667. Only three carriers provided complete responses. Two carriers provided partial responses and one carrier did not respond at all.

[1] "Annual Mandate Report: Coverage for Lymphedema Diagnosis, Evaluation, and Treatment." Available online: http://dlslibrary.state.md.us/publications/EXEC/DHMH/MHCC/IN15-1501(e)(1)_2016(2).pdf.

The carriers reported providing the coverage described under HB 113/HB 667 for 99 - 100% of insured plans, with some limitations noted. It is important to note that NovaRest also spoke with providers who disagreed that carriers are providing coverage to the extent represented in this report. Based on their analysis, NovaRest concluded that the mandate under HB 113/HB 667 would not have a substantial impact on healthcare costs in Maryland.

The Maryland Insurance Administration ("MIA") Workgroup took note of the substantial amount of research and analysis done by NovaRest and the report to the HCC. This MIA Workgroup's Report builds upon and supplements the foundation set by NovaRest in that HCC Report.

Maryland Insurance Administration Workgroup

This summer, the MIA established an informal lymphedema work group ("Workgroup") at the request of HGO Chairwoman Shane Pendergrass. The goal of this Workgroup was to pinpoint the gaps in coverage, as well as the gaps in provider and consumer knowledge about the coverage, and determine what actions may be needed to ensure that lymphedema patients receive coverage for medically necessary treatment. The Workgroup consisted of three MIA employees, a lymphedema patient advocate, a lymphedema therapist, and a carrier representative. The Workgroup held two public meetings in September 2017 to gather both information and insight into the issues affecting consumers and providers. The MIA sent notice of the Workgroup and public meetings to the list of those who testified on the bills during the legislative sessions, the people on the list of MIA contacts, and those who identified themselves as stakeholders or interested persons. The MIA also created a quick link on its website for the Lymphedema Workgroup and included an email address in order to solicit comments from stakeholders and the public.

The Workgroup held two public meetings on September 5th and September 14th at the Maryland Insurance Administration to allow stakeholders and other interested parties to voice concerns about the current state of insurance coverage for lymphedema related treatments, equipment, and supplies, to discuss the proposed legislation, and to provide any additional information related to the coverage and provider treatment of lymphedema.

At the September 5th meeting, the Workgroup heard testimony and comments from lymphedema patients, as well as family members of lymphedema patients. The Workgroup heard from lymphedema therapists, durable medical equipment vendors, lymphedema patient advocates, and an anesthesiologist. One insurance carrier representative provided testimony on behalf of the insurance carrier.

At the September 14th meeting, the Workgroup heard follow up testimony from the insurance carrier representative and one of the lymphedema patient advocates, each of whom had participated in the first hearing. In addition to the public hearings, the MIA received written testimony from providers and lymphedema patient advocates.

After the public meetings, the Workgroup put together a survey designed to build upon the work of the NovaRest survey conducted in 2016. The Workgroup survey was sent out by the MIA Market Conduct Section to the 14 carriers selling individual, small group, and large group health insurance plans in Maryland.[2] This Workgroup survey consisted of 12 questions designed to allow the Workgroup to address HGO's request to pinpoint gaps in coverage and determine what may be needed to ensure coverage for lymphedema patients receiving coverage for medically necessary treatment.

[2] Each of the 14 carriers is part of one of five carrier groups. When NovaRest references six carriers in its report, it appears to be referencing carrier groups, not the individual statutory entities. The references to carrier groups in this Workgroup's report are the same carrier groups referenced by NovaRest in its report, minus Evergreen Health.

Lymphedema Basics

There was written testimony submitted and in-person testimony presented at the public meetings on numerous topics. These included the definition of lymphedema, the stages of lymphedema, lack of lymphedema knowledge by providers and consumers, and the treatment of lymphedema. The treatment related topics addressed included the stages of lymphedema, provider appointments, and equipment and supplies used to treat lymphedema.

Definition

Part of our public meetings agenda was to discuss the definition of lymphedema as it appears in the Fiscal and Policy Note to previously proposed HB 113. There was testimony from members of the public that this definition as used was too limiting. Lymphedema is not simply swelling and inflammation. One lymphedema patient advocate stated that the definition does not take into account that lymphedema is a type of immune dysfunction since, if left untreated it, can develop into an immune deficiency. Another advocate stated that the definition limits lymphedema swelling to the extremities, which is not accurate. There may be swelling in other parts of the body such as in the torso, face, neck, or genitals. The testimony and survey responses discussed later in this report show that there is not a consistent definition of lymphedema in use by the carriers. The carrier representative testified that the carriers in her carrier group all use a broader definition of lymphedema than the one found in the Fiscal and Policy Note to previously proposed HB 113.

Stages of Lymphedema

Another issue the Workgroup heard testimony about is at what point treatment for lymphedema is deemed medically necessary by carriers in order to be covered by health insurance plans. In the testimony we heard, individuals voiced their concerns that health plans

will only deem treatment of lymphedema to be medically necessary once the condition has progressed into the later stages. One person testified that any legislation should not require or suggest that there needs to be a clinical diagnosis for lymphedema treatment to be covered.

Several people who testified advocated for carriers to begin coverage of lymphedema treatment in the earlier stages. They argued that Stages 0 and 1 are incredibly important times for at risk patients because they may have little or no symptoms of developing lymphedema, but early intervention can prevent lymphedema or its progression. It was pointed out that if carriers would provide coverage for treatment in the earlier stages of lymphedema they will save money because the treatment methods become more costly in the later stages of lymphedema. Treatment at the earlier stages, Stages 0 and 1, generally means a patient's condition is managed with minimal difficulties and ultimately results in less costly overall treatments. In contrast, treatment beginning at Stages 2 and 3 where symptoms are advanced and the condition becomes more problematic are more difficult and expensive to manage. Patients in these stages are also more at risk for cellulitis, which can result in death.

Furthermore, many of the treatment methods in stage 0 and 1 only require over-the-counter supplies as opposed to those prescribed by a physician. Individuals at the hearing pointed out that these supplies are less costly as a method of treatment, yet carriers will not cover the supplies either because these supplies are distributed over-the-counter or are not pursuant to a prescription or medically necessary determination.

One lymphedema patient advocate pointed out that there are no ICD-10 codes for pre-clinical lymphedema or for early lymphedema detection methods. Therefore, the detection methods are not often covered by health plans. He also stated that early interventions or treatment are generally more cost effective and stated it can cost $40,000-$80,000 to treat

cellulitis which can occur in later stages. Hospitalization may also occur more often for patients in the later stages of lymphedema, which is more costly to carriers.

Treatment

The Workgroup received written testimony and also heard oral testimony that there is general agreement among lymphedema researchers, clinicians, and therapists that compression is the key protocol in the treatment and management of chronic lymphedema. Treatment of lymphedema involves a number of different protocols that are selected by the treating physician and therapist depending on the stage, severity, duration and etiology of the individual patient's condition. These protocols usually include manual lymph drainage (MLD), static and dynamic compression, exercise, and skin care. Current treatment guidelines include static compression as the mainstay of the treatment of chronic lymphedema. This multi-protocol treatment is known by many names, the most common being "complete or complex decongestive therapy" ("CDT"). The compression usually involves the application of a system of compression bandages by a therapist during the clinical intensive phase of treatment, and the use of self-applied bandages, compression garments and devices in a home setting after clinical treatment. Compression bandage systems are typically composed of bandages, a tubular sleeve or stocking, unwoven or foam padding, foam pieces, short-stretch bandages, and tape. Often these are procured as a kit for an arm or a leg. Because each element of the bandage system has a distinct function the bandage system typically requires all of the elements. Compression is typically applied day and night with the method and duration prescribed by the treating physician and therapist as appropriate for the patient's medical needs.

The Workgroup heard extensively at its public meetings and in written submissions that carriers do not adequately cover compression garments and bandaging materials and supplies. In

contrast, one carrier stated that its plans covered all medically necessary garments and supplies except those dispensed over the counter. Compression garments take many forms, depending on the body site (e.g. arm, leg, hand, foot, breast/chest, trunk, abdomen), form (e.g. circular-knit elastic, flat-knit custom, directional flow chip bag, strapped garment) or the patient's ability to apply (e.g. zippered, Velcroed) the garment. However, we heard testimony about failures by carriers to cover compression garments as the result of contract limits or exclusions, including those for body parts that are not extremities or the result of conditions developing outside of a course of follow up treatment for breast cancer surgery.

One Certified Lymphedema Therapist stated that due to differences in insurance company plan coverages, she cannot treat patients equally because of a lack of access to the same compression garments. Examples cited by others at the public meetings described how they had to pay out of pocket for supplies except those that are dispensed over the counter, compression garments, both prescribed and non-prescribed, based on contract exclusions or limitations. We also heard that even if compression garments are covered by insurance, they sometimes do not provide adequate coverage for the number of garments and supplies necessary for patients who wear them both during the day and at night.

The carrier representative testified that the carriers in her group cover all medically necessary supplies except those that are purchased over the counter, and that there are no benefit limits on the number of garments allowed from in-network suppliers.

A**ppointments**

Some who testified at the public meetings voiced concerns about carrier coverage of the different treatments and detection methods. There was testimony that there may be limits that health plans place on the number of visits to physical and occupational therapists who treat

lymphedema. It was stated that some health plans may place 15 to 30 visit limits on treatment or rehabilitation benefits. One person briefly described congestive decompression therapy and stated that it may take 2-3 weeks with multiple visits each week before a patient's limb or region has stabilized enough to be fitted for a custom garment. Once the limb or region has been fitted for a custom garment, therapy must continue to maintain that size while the patient waits to receive the garment.[3] Another person told the Workgroup that 75% of patients reach their "goal" within the rehabilitation therapy visit limits. However, some patients require more therapy to attain their treatment goal. In addition, patients may plateau at a certain point during their therapy. If patients are not showing improvement, the therapy may not continue to be covered by the insurance company. This leads to a renewed problem because if patients do not continue therapy once they have plateaued, their condition will worsen.

The carrier representative testified that the carriers in her group do not have any limits on medically necessary treatments.

Provider Knowledge

The Workgroup heard testimony from individuals who did not feel that medical providers as a whole have enough expertise to adequately diagnose and treat lymphedema. One Certified Lymphedema Therapist testified that it often takes providers far too long to recognize and therefore accurately diagnose lymphedema. An internist with a focus on adult medicine submitted testimony that stated lymphedema is often under-recognized during a patient's hospitalization, resulting in inadequate post-discharge follow-up plans and instructions. He offered reasons for gaps in provider knowledge including: providers not feeling equipped to

[3] This led to a discussion of the difficulties some patients have obtaining custom garments including excessive wait times for manufacture and delivery. The issue of participating providers who are available to provide the garments is not directly related to actual benefits provided under the contract. Therefore, the Workgroup has not done an in depth analysis of these issues but notes it for the General Assembly.

educate patients or manage lymphedema; a lack of provider awareness of available resources for lymphedema management; lack of understanding that lymphedema is a chronic issue which must be addressed during hospital stays; lack of awareness that ongoing management is indicated; and an undiagnosed or misdiagnosed condition.

Consumer Knowledge

Testimony from individuals who noted gaps in their particular plan coverage were asked at both the legislative and public meetings if their coverage was fully insured coverage or self-funded health coverage. Many individuals did not understand the distinction. We made clear at the public meeting that the MIA only regulates fully-insured plans and not self-insured or self-funded health plans. This was revealed to be a big gap in consumer knowledge for lymphedema patients, although the MIA notes that this particular distinction exists across all types of health plans and patients.

Another area the Workgroup heard testimony on was the average patient's lack of knowledge on whether the therapist treating them is qualified to treat lymphedema.

The MIA Workgroup Survey

The MIA's carrier survey was designed to supplement the HCC Report and the work done by NovaRest. We asked specific questions of all 14 carriers and received responses. The questions and the summaries of the responses follow. The conclusion reached in numerous instances is that there are specific gaps in coverage. Although we found gaps in coverage, it is important to state that some carriers are offering substantial coverage, others lesser but still substantial coverage, and others very limited lymphedema coverage. In places where it makes sense for purposes of this report, we have combined the analysis of the questions and sub-questions.

1. **Provide the definition of lymphedema that the carrier refers to when determining whether to provide benefits or coverage for a treatment of lymphedema.**

The responses to this question revealed that the carriers are not using the same definition of lymphedema in making lymphedema related determinations. We requested that the carriers provide the definition of lymphedema that they refer to when determining whether or not coverage will be provided for the treatment of lymphedema. Five of the carriers provided definitions. One carrier provided a one sentence definition that states lymphedema is fluid build-up due to lymph node removal or the "blockage or destruction of lymphatics." Three carriers provided a more detailed definition which addresses both primary and secondary lymphedema, the location in the body where lymphedema may occur, and different options for the treatment of lymphedema. Another carrier definition simply referred to swelling and fluid build-up in different parts of the body. The other carriers did not provide a definition or stated that they do not refer to any definition in order to provide benefits for the treatment of lymphedema. Instead, they rely on a medical necessity determination or a diagnosis to provide available benefits, if any.

1a. Indicate the causes or conditions for which medically necessary treatment of lymphedema is provided for under the carrier's plans (e.g. specific diseases, procedures, or codes).

With question 1a, we sought to determine what the carriers see to be the causes and conditions of lymphedema and asked for specific ICD-10 codes. In response, six of the carriers provided specific ICD-10 diagnosis codes with a description of each code as their sole response. The same three codes appeared in all six responses: I89.0, I97.2, and Q82.0. However, three of the carriers provided a range of codes (I89.0-I89.9) while the other three only listed code I89.0. The I89.0 code description provided by the carriers is for "lymphedema, not elsewhere

classified." The I97.2 code is specific to lymphedema following a mastectomy, and the Q82.0 code is for primary lymphedema.

One carrier group stated that it does not look at the causes or conditions when making a determination of medical necessity. Instead, it relies on the diagnosis of the treating physician. In addition, they use several sources of medical criteria to determine whether or not the treatment is medically necessary. This carrier group specifically points out that treatments required by Federal Women's Health and Cancer Rights Act of 1998 ("WHCRA") are covered if they are medically necessary and not excluded elsewhere in the plan. These two stated qualifiers are important. The WHCRA treatments identified by the carriers are specific to mastectomies. This carrier group's response is significant because it begins a continuing series of answers for all of its statutory carriers. The result is that this carrier group's carriers only provide medically necessary coverage as required by the federal WHCRA. This is the most significant and obvious coverage gap discovered as a result of the survey.

Two other carriers, within a different carrier group, refer to the same three ICD-10 codes in their response without providing the range of codes within the I89 code. They also indicate that they rely on the diagnosis of lymphedema from the physician to determine coverage. These carriers state that they do not focus on the causes of lymphedema when determining if treatment is medically necessary.

From these responses, it appears that overall, the diagnosis codes being used for lymphedema are consistent between carriers. We recognize that some carriers appear to focus on the diagnosis codes which seem to encompass a variety of causes of lymphedema, especially with the incorporation of the I89 code, which takes into consideration any form of lymphedema that is not classified elsewhere. Carriers that are not as narrowly focused on the ICD-10 Codes

rely on other medical criteria and physician opinion as part of the determination for coverage. These same carriers may limit causes of lymphedema to specific prerequisite conditions such as cancer and surgeries.

2. Does the carrier recognize the different stages of lymphedema as part of the carrier's determination of medical necessity? If so, what stages does the carrier recognize and at what stage is treatment considered medically necessary?

In question 2, we sought to determine the carriers' knowledge and recognition of the different stages of lymphedema. We also sought to determine if the carriers base their determination of medical necessity for treatment in these stages. We wanted to know if carriers consider treatment of lymphedema to be medically necessary once it has reached a particular stage.

Twelve of the carriers stated that they do not take the stages of lymphedema into consideration when making coverage determinations. Two of the carriers specified that their policies look at the coverage of the type of treatment as opposed to focusing on the stage of the lymphedema, or the ideal treatment method. The two carriers that do recognize the different Stages of lymphedema (Stages 0-3) do not specify if the stages are taken into account when determining coverage for treatment of lymphedema. One of these carriers references stages 0 through 3, while the other carrier references only stages 1 through 3.

Based on these responses, it appears that all but one of the carriers surveyed do not take into account the stages of lymphedema when making a coverage determination or claim decision. Only two carriers stated that they do recognize the stages and one of these carriers pointed out that coverage is provided for stages 0 through 3.

2a. Are early interventions, designed to prevent or prevent in at-risk patients the progression of clinical lymphedema, covered?

In question 2a, we asked carriers if preventive or early intervention treatments are covered. We did not receive any "no" responses to this question. One carrier group provided a more detailed response than the other carriers. It identified the therapies and stated that early intervention methods are covered for those who are considered "at-risk patients" and as means to "prevent the progression of lymphedema."[4] This carrier group adds that self-management training, education, equipment, and supplies are covered under their policies.

The other 11 carriers provided short responses indicating preventive and early intervention treatment is covered. Two carriers simply responded "yes" that all is covered. Several other carriers specified that the preventive and early intervention treatment is covered if medically necessary but also proven. Four carriers used qualifying language such as "may be covered" when responding. Two of the eleven carriers responded that conservative treatment in a physician's office for prevention purposes is "generally covered."

Overall, it appears that early intervention is covered by plans when it is deemed medically necessary. However, given the stated difficulties providers have recognizing and diagnosing lymphedema, this medically necessary requirement can be a barrier to coverage for those with early stage lymphedema. Also, according to some carriers, early intervention may not be covered by all plans. Certain carrier responses show that these companies require proof that a preventive treatment or early intervention method is effective when making determinations or decisions that involve specific types of early intervention.

3. Using the chart, state if the carrier covers provider appointments for the diagnosis, evaluation, and treatment of lymphedema?

[4] The response is prefaced with "When benefits are provided in the member's contract…", but this appears to be referring to grandfathered products.

For question 3, we asked the carriers to fill in the chart as to whether or not coverage is provided for provider appointments for the "diagnosis, evaluation, and treatment of lymphedema." The chart was set up for the carriers to specify if all of their plans, some of their plans, or none of their plans provided coverage for provider appointments. Ten carriers indicated that all of their plans provide coverage for these types of provider appointments. One carrier group's answers to Question 3 simply referenced its responses to questions 3a and 3b, where it indicates that coverage is provided when the diagnosis testing and evaluation is medically necessary and proven. Their response failed to specify if all of their plans or some of their plans provide coverage. Therefore, the specific request in question 3 was not fully addressed by these four carriers.[5]

There appears to be a consensus among the carriers that fully responded to this question that all plans cover provider appointments for "diagnosis, evaluation, and treatment of lymphedema."

3a. Does the carrier cover differential diagnosis evaluation and testing?

In the survey, question 3a is a narrowed down version of question 3 where we asked the carriers if coverage is provided for "differential diagnosis evaluation and testing." In response to this question, five carriers provided a one word response, "yes." Five other carriers specified that the diagnosis evaluation and testing are covered when considered medically necessary. One carrier group replied that differential diagnosis and testing is covered when medically necessary and proven. An asterisk is attached to their responses that specify that bio impedance spectroscopy is not covered since it has not been medically proven as a viable test based on

[5] Carriers that provided incomplete or non-responsive answers are being followed up with by the MIA's Market Conduct Section as appropriate.

"peer-reviewed medical literature and is therefore, not medically necessary. There are clearly differences in carrier coverage in this area.

3b. Does the carrier cover diagnosis of early (Stage 0) lymphedema?

Question 3b is another question related to the diagnosis of lymphedema and focused on diagnosis of stage 0 lymphedema. The responses to this question were similar to the responses to question 3a. Three carriers simply replied, "Yes." Three other carriers specified in their responses that coverage is provided and that they do not distinguish between the different stages of lymphedema. Two carriers responded yes, with an explanation of the means in which it is covered. The remaining six carriers provided the same response they provided to question 3a. Of those six, the four that specifically provided exclusion for bio impedance spectroscopy reiterated the same point in this response.

As with our analysis to question 3a, it appears that in general, all of the carriers surveyed state they provide coverage of the diagnosis of stage 0. However, several indicated that they rely on criteria, medical literature, and medical necessity when making a determination. Furthermore, with the short "yes" responses from some carriers, we are unable to determine if they have any pre-conditions when it comes to coverage for diagnosis of stage 0.

4. **Using the chart, state whether the carrier provides benefits towards the following types of compression garments?**

    a. **If the carrier provides benefits for Gradient compression garments described in the chart, is coverage provided for more than one garment at a time for the same body part (for example, night garment/day garment, or multilayered garments to enable easier donning in providing increased compression)?**

b. **If the carrier provides benefits for Gradient compression garments for *some* plans only, please specify which plans cover this benefit and which plans exclude this benefit**.

c. If the carrier provides benefits for Gradient compression garments described in the chart (#4), please describe any limits, restrictions, or exclusions related to the benefits provided.

The carriers' responses to this question and the follow up sub-questions vary. With Question 4 we were looking to determine coverage of the following types of compression garments: prescribed and custom fit gradient compression garments, non-prescription compression garments, over the counter ("OTC") prescribed compression garments, and non-prescribed OTC compression garments. With Question 4a we sought to drill down on the number of garments by the plans. Question 4b was designed to find out, if applicable, which specific plans or plan types did not cover compression garments. Question 4c was posed to give us specifics on any limits, restrictions, or exclusions to the stated benefits provided.

The differing carrier responses are most easily looked at together. These responses clearly demonstrate that there are gaps in coverage of compression garments. Those contracts that do cover gradient compression garments require them to be medically necessary and prescribed by a physician. Three carrier responses cover physician-prescribed custom and non-custom compression garments in almost all of their contracts, as medically required, with no limitations. Two other carriers have a limit of two garments per limb per year. One carrier group has fairly restrictive coverage in comparison to the others. Those responses indicated that gradient compression garments were not covered except for lymphedema stockings for the arm and chest/breast as required as a result of breast cancer. No carriers cover over the counter compression garments.

The qualifying language of "medically necessary" used by some carriers makes it difficult to tell exactly what is covered by some plans. Carriers answering that medically necessary coverage is available in *some* plans makes clear that not every plan covers compression garments, even if medically necessary. Medically necessary compression garments for post-mastectomy lymphedema are covered per Federal mandate ("Federal Mandate"). The responses show that all carriers do provide this coverage. But beyond that coverage is not so clear.

Compression garments seems to be an area where there is inconsistency in categorization which leads to confusion about coverage. Some carriers cover compression garments as Durable medical Equipment ("DME") and others as supplies. One carrier group excludes supplies except for coverage of supplies under the WHCRA. Another carrier group stated that compression garments are treated as DME but may be excluded as such under grandfathered large group plans. Another carrier group does not cover at all except per the WHCRA.

There may be contracts where these garments are incorrectly categorized as supplies which will result in an exclusion of coverage because that category of supplies is excluded. There is a good argument that hose or low compression stockings are considered supplies. However, garments used in the treatment of lymphedema are reusable every day and have an intended life of six months. This raises a question as to whether these are appropriately classified as supplies or would be more appropriately classified as a prosthetic device benefit consistent with the Medicare program definition.

There can be other reasons for exclusion of compression garments. Two carrier responses indicated that the gradient compression garments were covered, but that that "there may be a limit on some plans specific to OTC compression garments."

5. **If the carrier provides benefits for gradient compression garments, please indicate with a "yes" or "no" whether gradient compression garments for the following body parts are covered: Arms; Hands/Fingers; Feet/Toes; Chest/Breast; Trunk Thorax; Head/Neck; and Abdomen.**

    a. **Please explain the reason for any no answer to question #5.**

    b. **If the carrier provides benefits for the listed equipment and supplies described in the chart, under what benefit category is it provided?**

With Questions 5- 5b we sought greater specificity on coverage of gradient compression garments for specific body parts and categorization of those benefits under the insurance policies. Like the responses to Questions 4- 4c, these questions again prompted differing responses that demonstrate that there are some gaps in coverage. One carrier group again responded that it does not cover compression garments except for the arm (and chest/breast as required) under the WHCRA. All other carriers provide coverage for garments that treat lymphedema in a patient's extremities including arms, hands, fingers, legs, feet and toes. However, while these three carrier groups cover garments for all extremities, two carrier groups currently view compression garments for trunk, chest, abdomen, and groin, to be experimental, investigational or unproven and therefore not medically necessary.

There is also again a range of responses in how the carrier groups categorize these garments. Some put these squarely in the benefit category for DME while others put them in with Medical Devices, or Supplies, or prosthetics. One carrier even stated that these are covered within the core benefits of the health plan.

6. **Using the chart, please state by HCPCS code if the carrier provides benefits for listed pneumatic compression devices and appliances, including:**
    Pneumatic Compression Device or Supply;
    Pneumatic Compressor (non-segmental) E0650;
    Pneumatic Compressor w/o Gradient Pressure (segmental) E0651;
    Pneumatic Compressor w/ Gradient Pressure (segmental) E0652;

Non-segmental Pneumatic Appliance E0655;
E0660; E0665; E0666;
Segmental Pneumatic Appliance E0656; E0657; E0667; E0668; E0669; E0670;
Segmental Gradient Pneumatic Appliance E0671 E0672 E0673;
Pneumatic Compression Device E0675; and
Intermittent Limb Compression Device and Replacement Sleeve

a. **If the carrier provides benefits for pneumatic compression devices and supplies for *some* plans only, please specify which plans provide this benefit and which plans exclude this benefit. If the carrier provides benefits for pneumatic compression devices and supplies, please describe any limits, restrictions, or exclusions related to the benefits provided.**

b. **If the carrier provides benefits for pneumatic compression devices and supplies, please describe any limits, restrictions, or exclusions related to the benefits provided.**

With Questions 6- 6b we were seeking to determine how carriers cover pneumatic compression devices and appliances. The differing responses demonstrated once again that there are gaps in coverage. The responses are more easily described together. The carriers that provide coverage for these do so as Durable Medical Equipment ("DME") subject to the terms, conditions and limitations of the applicable plan DME benefit.

Three of the five carrier groups provide coverage in all plans for Pneumatic Compression Devices or Supplies; Pneumatic Compressor (non-segmental) under code E0650; Pneumatic Compressor without Gradient Pressure (segmental) under code E0651; Pneumatic Compressors with Gradient Pressure (segmental) under code E0652; and Non-segmental Pneumatic Appliances under codes E0655, E0660; E0665; E0666. However, these three carrier groups all condition coverage on medical necessity. Two carrier groups state additional conditions, such as being covered when meeting the plan criteria of proven clinical indications in the policy, or criteria per CMS' Medical Coverage Policy, and Milliman Care Guidelines, in which each may have their own limitations, restrictions and exclusions. Another carrier group stated that

Segmental Pneumatic Appliances under codes E0656, E0657, E0670, for trunk, chest, and two full legs and trunk are considered experimental and are not covered. One other carrier group stated that pneumatic compression device and supplies are covered as DME only after a review on a case by case basis.

7. **If coverage is provided for pneumatic compression devices, please indicate with a "yes" or "no" whether pneumatic compression appliances are covered for treatment of the following: Arms, Legs, Chest, Trunk, Head/Neck, and Abdomen.**

With Questions 5-5b we sought greater specificity on coverage of pneumatic compression devices for specific body parts and any reasons for coverage not being provided. Like the responses to the previous few questions, the differing responses clearly demonstrate that some carrier plans have gaps in coverage. All carriers state that coverage for pneumatic compression devices used to treat the extremities is covered. Two carrier groups indicate that no coverage is provided for pneumatic compression devices that treat the chest, trunk, head, neck, or abdomen because it views such treatment as investigational, experimental, and unproven. Another carrier group states that determinations on pneumatic compression devices are subject to the covered indications listed in the LCD L33829 Pneumatic Compression Devices or Medicare Guidelines.

8. **Does the carrier provide benefits for the equipment and supplies related to the diagnosis, evaluation and treatment of lymphedema as listed in the chart including Equipment and Supplies, and more specifically Finger/Toe Bandages, Short-Stretch Bandages, Foam/ Padding, Tubular Sleeves, Donning Gloves, and Tape?**

During the legislative and public meetings there was lots of testimony and discussion about coverage for bandages and the supplies that accompany their use. Question 8 was designed to help pinpoint any gaps in the coverage of the materials commonly used in the

treatment of lymphedema. As stated previously, compression bandage systems have several components. Most carriers treat these treatment devices as DME or supplies.

The carrier responses to this question and the sub-questions varied, demonstrating gaps in coverage among the carriers. At a high level, the carriers indicate that coverage for these types of supplies is provided under most, but not all plans. Drilling down to specifics reveals that the carriers use a variety of qualifications or exclusions to coverage. Qualifications include medical necessity, coverage under the contract for DME, coverage under the contract for supplies, or coverage only when members have venous stasis ulcers. In addition to the aforementioned, other exclusions and limitations include restrictions on OTC supplies, limits on benefits for equipment and supplies to twice per year unless otherwise determined to be necessary by a physician, limits on benefits for prescribed supplies if available OTC as determined by the carriers, and in one instance an exclusion for all tape.

9. Does the carrier provide benefits for complex decongestive therapy? (also referred to as Complete decongestive therapy.)

a. If the carrier provides benefits for complex decongestive therapy, what type of benefit are they considered to be under the policy? Does the carrier provide benefits for any therapies other than complex decongestive therapy for the treatment of lymphedema? Please explain.

b. If the carrier provides benefits for complex decongestive therapy for *some* plans only, specify which plans provide this benefit and which plans exclude this benefit.

c. If the carrier provides benefits for complex decongestive therapy, describe any limits, restrictions, or exclusions related to the benefits provided.

With these questions we were looking at the level of coverage provided for complex decongestive therapy and the type of therapy carriers considered to be covered within this policy.

From the carrier responses, there appears to be consistency concerning the availability of coverage across all plans. However, the responses suggest that gaps may exist based on the CPT code used to bill for the visit.

Each of the carriers responded that benefits for complex decongestive therapy are provided for all plans. Coverage determinations are based on medical necessity and include services that align with company policies and contracts. Covered benefits may be medical in nature or DME.

The responses from the carriers varied concerning the other benefits provided, including the following: manual therapy techniques, services as part of short term rehabilitative therapy, compression garments and bandages, equipment, supplies, therapy, self-management training and education. While each carrier indicated that benefits are provided across all plans, the responses varied concerning limits, restrictions, or exclusions related to the benefits provided. Since these are in large part based on medical necessity and alignment with medical policy, it is unclear exactly what gaps may exist. But the inconsistencies do reveal gaps in coverage. One carrier group responded that coverage for members is limited to that for a venous stasis ulcer. Another carrier group responded that any conditions or limitations are subject to the plan's short-term rehabilitative therapy benefits. Still another indicated that their response was based on reimbursement policy for CPT code 97140 for treatment of complex decongestive therapy. In that instance, the carrier responded that coverage is allowed under and limited to the Rehabilitation Services Outpatient benefit. It is not clear whether the required materials to support self-treatment in a home setting would be covered (self-MLD, bandaging and compression garments) since there is no CPT code that applies to non-skilled procedures.

10. Does the carrier provide benefits for any lymphedema related self-management, training and education?

Each of the carriers responded that coverage is provided for lymphedema related self-management, training and education. The responses indicate that coverage is available across plans. One carrier responded that depending on the CPT code used, services that are training and educational in nature may not be covered by standard benefit plans if the services are billed separately. One carrier indicated that coverage is available across plans for services reimbursed under CPT code 98960-98962, as well as codes for standard office visits. From the carrier responses, there appears to be consistency in coverage for lymphedema related self-management, training and education across all plans. Again, any potential gaps in coverage appear to be based on the appropriate code used to seek reimbursement for the service.

11. Is there any type of prior authorization required for any of the following treatments: gradient compression garments; pneumatic compression devices; diagnosis, evaluation, and treatment; equipment and supplies; complex decongestive therapy; and self-management, training, and education.

From the carrier responses there appear to be significant differences in preauthorization requirements. Two of the carrier groups responded that it has no preauthorization requirements for the treatments listed above. In contrast, one carrier group responded that preauthorization is required for all the above-mentioned services and treatments. One other carrier group requires preauthorization for services associated with segmental pneumatic appliances. Another carrier group responded that preauthorization determinations are based on one or more of the following factors: (1) for gradient compression garments, whether the services is required by the WHCRA of 1998 and the cost of the garment; (2) for pneumatic compression devices, whether the cost exceeds $1,000; (3) for diagnosis, evaluation, and treatment, services must be proven and medically necessary; (4) equipment and supplies are excluded; (5) for complex decongestive therapy, prior authorization may be required for physical therapy; and (6) there is no preauthorization required for self-management training and education.

12. Are any prerequisites required for coverage for the following: gradient compression garments; pneumatic compression devices; diagnosis, evaluation, and treatment; equipment and supplies; complex decongestive therapy; and self-management, training, and education, including conservative treatments or hospitalizations?

There are great differences among the carrier group requirements to be met before coverage of the listed items is provided. One carrier group listed prerequisites for all six of the items on the list in the form a primary physician referral. Another carrier group listed specific prerequisites for all of these except complex decongestive therapy. Three carrier groups require the failure of some form of conservative therapy before complex decongestive therapy and pneumatic compression devices are covered. This wide disparity in the carrier answers demonstrates that there are gaps in coverage.

Recommendations

The MIA was asked to provide recommendations for the General Assembly to consider with any proposed lymphedema legislation in 2018. The MIA is not making any specific coverage recommendations to the General Assembly. However, it is very clear that there are differences in how the carriers currently cover lymphedema treatment, equipment, and supplies. These differences result in some gaps in coverage in most carrier plans. The gaps are far more significant for those who have coverage through one specific carrier group's statutory insurance companies. For these insureds, there is no coverage for lymphedema outside of the requirements of the WHCRA.

The MIA encourages the General Assembly to consider the following if considering lymphedema related legislation:

- Defining lymphedema that is not limited to symptoms in just limbs or extremities or symptoms resulting from the treatment of Breast cancer;

- Defining Compression garments and/or classifying compression garments as DME, supplies, or prosthetic devices, etc.;
- Mandating coverage of compression garments, compression bandage systems, and/or coverage of the necessary supplies to be used with the garments themselves;
- Establishing minimum limits for the number of garments covered per period;
- Establishing a minimum limit for the number of patient visits or treatments; and
- Mandating coverage for sequential pneumatic compression devices and compression appliances.