COMMENTS FOR NOVITAS OPEN MEETING

AUGUST 13, 2021

David J. Freedman, DPM

Maryland Podiatric Medical Society and JL Contractor Advisory Committee (CAC) Member

Novitas LCD Surgical Treatment of Nails (DL34887) Review and Comments:

1. “Patients with factors that predispose them to infection are those with uncontrolled diabetes mellitus, prior infection with methicillin-resistant Staphylococcus aureus, and immunosuppression.3”

COMMENT: Diabetes does not necessarily need to be “uncontrolled” to predispose a patient to an infection of this type. Similarly, there are many immunocompromised states that predispose a patient to an infection of this type. Given this, we suggest this sentence be edited to read: “Patients with factors that predispose them to infection are those with diabetes mellitus and immunocompromised states.”

1. No consensus has been reached for the best treatment approach, but ingrown nails may be treated non-surgically or surgically. Non-surgical treatments are typically used for mild to moderate ingrown nails, whereas surgical treatments are used in moderate and severe cases.1,4,7

COMMENT: Non-surgical treatment of ingrown nails, this sentence should be instead: Patients who are not surgical candidates, patients who can resolve the problem through local medical treatment, whereas..." This LCD also is advising or recommending treatment based on the opinion that if a condition is mild or moderate, then it should have xxxxx procedure. If a condition is moderate to severe, then it should have an alternate procedure. In my opinion, an LCD should not be recommending treatments. This should be left to the treating practitioner. This should only deal with “reasonable and necessary” guidelines and not guidelines based on severity.

1. A small not too painful hematoma is incorporated into the nail and progressively migrates outward to the free edge of the nail plate as the nail grows out.

COMMENT: However, there are patients such as neuropathic patients that may not be experiencing pain that may still require that subungual hematoma incised, drained, removed, evacuated, or avulsed. Not all nails grow out the hematoma, for this reason this sentence should be omitted.

1. In traumatic nail injuries, surgical nail avulsion may be used to evaluate the stability of the nail bed or to release a subungual hematoma after a failed puncture aspiration. Injury of a fingernail may be treated with avulsion…

COMMENT: This is not limited to fingernail, should be "fingernail or toenail"

1. The thickening of the nail plate may be a symptom of nail fungus or psoriasis. This thickening (Onycholysis) may force the nail plate to separate from the nail bed. This condition may last for several months because the finger or toenail will not reattach to its nail bed. Non-surgical treatment consists of clipping off the affected separated portion at the distal end of the of the nail plate and treating the underlying cause. In the case of moderate or severe symptomatic dystrophic nail plate, a surgical intervention may be required.1,4,7

COMMENT#1 An LCD should not limit possible and medically appropriate diagnoses. Either list ALL of the reasons or eliminate these suggestions of a diagnosis.

COMMENT#2 Onycholysis is loosening not thickening.

COMMENT#3 Suggest change,’’…..their condition may be asymptomatic…….” to “….their condition may not cause pain….”

COMMENT#4 If a condition is moderate to severe, then it should have an alternate procedure. In my opinion, an LCD should not be recommending treatments. This should be left to the treating practitioner. This should only deal with “reasonable and necessary” guidelines and not guidelines based on severity.

1. …the surgical removal of the body of the nail plate from its primary attachments, the nail bed ventrally and the PNF dorsally.

COMMENT: PNF, is not a standard abbreviation and is not appropriate, it should be spelled out, each word.

1. Excision of nail plate and nail matrix is performed under local anesthesia and requires removal of part or all of the nail thickness and length, with destruction or permanent removal of the matrix (e.g., chemical/surgical matrixectomy). Partial matrixectomies may be performed in the management of persistent onycholysis and onychocryptosis. When a chemical matrixectomy is performed, the nail will not regrow and will result in permanently eliminating the problem the nail was causing.7 When performed without, matrixectomy in most cases, the nail will regrow from the area under the cuticle (the matrix). A fingernail takes about 4 to 6 months to grow back. A toenail takes about 8 to 12 months to grow back.8,9

COMMENT #1 There is an error in this instruction. Excision of a nail plate/matrix does NOT require "...removal of part or all of the nail thickness and length..." it just requires removal of the full length or the entire nail plate. The removal of part of the thickness is not applicable and is an unreasonable statement.

COMMENT#2 This second statement highlighted has no place in an LCD or anywhere else. A matrixectomy is not always permanent although we would like to think that it is, a 4% recurrence rate is related in the information Novitas cited by the Cochrane study.

COMMENT#3 There is no guarantee that 100% time the procedure will not regrow a portion of the nail, (1/25=4% Cochrane systematic review cited in Novitas evidence.) regrow and might see regrowth as early as 2-3 months so waiting for this 8-12 months is inappropriate medical care nor standard of care to remove more nail and matrix outside its global procedure which is 10 days. Article in this Proposed LCD says: “average fingernail growth rate 3.47mm/month) was over twice as fast as that of toenails (1.62 mm/month),”

1. Wedge excision of skin of the nail fold is designed to relieve pressure on the nail/soft tissue and is an excision of a wedge of the soft granulation tissue and ingrown nail from the involved, medial and/or lateral, side of the toe or finger.

COMMENT: CPT 11765- "Wedge excision of skin of nail fold". It is not "...an excision of a wedge of soft granulation tissue...". Granulation tissue is not skin, nor is any nail removed.

1. Avulsion of the nail plate, excision of the nail and nail matrix, and wedge excision of the skin of the nail fold are considered medically reasonable and necessary for the following indications:

1. Symptomatic onychocryptosis (ingrown fingernails or toenails)1,3,4,7

2. Subungual abscess and/or hematoma8,10,11

3. Subungual tumors2,10

…8. Congenital nail dystrophies that jeopardize the integrity of the finger or toe1.

COMMENT#1 Diabetic neuropathic and idiopathic neuropathic patients may be pain free yet have an indurated border, and/or erythema, and or purulence medially or laterally not necessarily symptomatic with pain.

COMMENT#2 How about tumors that are not subungual but in the nail groove or under the proximal nail fold such as Melanoma that would require removal of the nail for access?

COMMENT#3 What about nail dystrophies that are not "congenital" but are acquired, this should include both options?

1. Limitations….3. Surgical treatment of asymptomatic conditions.4,7

4. Repeat nail avulsion on the same toe or finger following a complete nail avulsion performed more frequently than every 8 months (32 weeks) for toenails or 4 months (16 weeks) for fingernails.8,11

5. Repeat nail excision on the same toe or finger following a complete nail excision for permanent removal.

COMMENT#1 There has to be the exception for that diabetic neuropathic or idiopathic neuropathic patient, they will exhibit asymptomatic i.e., pain yet the procedure may very well be medically necessary.

COMMENT#2 See comment above based on above and study cited "“average fingernail growth rate 3.47mm/month) was over twice as fast as that of toenails (1.62 mm/month)," It is unreasonable to wait for a nail to grow all the way out if there is recurrence. When it is recognized, it is most appropriate to treat the recurrence that can be as early as 2-3 months based on the growth metrics stated.

COMMENT#3 Would be nice if "permanent removal" was 100% permanent. This is an unreasonable limitation. Should be based on medical necessity.

1. With this study, it was observed that the “average fingernail growth rate 3.47 mm/month) was over twice as fast as that of toenails (1.62 mm/month), P < 0.01.”

COMMENT: This was stated in summary of evidence, if using this as a basis for care then the restrictions stated in this LCD are not reasonable. The policy is supposed to provide “reasonable and necessary” care.

1. Also noted, careful patient selection and maintenance of asepsis during and after the procedure and gentle handling of the matrix and nail folds are noted to promote positive outcomes of the procedure. Nail generation depends on a patient’s age, gender, and habits. Complete regrowth of an avulsed fingernail usually requires 4-5 months, whereas the toenail may require up to 10-12 months.8,11

COMMENT: Again, the time frame limitations are unreasonable, and the further care required should only be based on “reasonable and necessary”

1. When a nail avulsion is done, the matrix is not typically destroyed, thus leading to regrowth of the spicule or nail plate.15 For those patients who have failed conservative therapy or have a symptomatic presentation of an ingrown toenail that is moderate to severe4; a surgical intervention such as removal of granulation tissue of the affected nail fold and a partial nail avulsion of the affected nail edge and with the application of a chemical, surgical, or electrocautery matrixectomy to prevent recurrences, may be required.15 A Cochrane systematic review found that a partial nail avulsion combined with phenolization is more effective at preventing symptomatic recurrence of an ingrown nail than surgical excision/removal without phenolization (one in 25 patients with recurrence versus eight in 21 without phenolization).12

COMMENT#1: What about patients who do not have the micro or macro circulation to heal from a matrixectomy? The LCD states "....may be required." Will Novitas be responsible if the patient does not heal and requires an amputation? This "requirement" is another inappropriate statement to put into an LCD.

COMMENT#2: 1/25=4% Cochrane systematic review cited. Once can expect there will be occasionally recurrence.

1. “Analysis of Evidence” …”frequently than every 8 months (32 weeks) for toenails or 4 months (16 weeks) for fingernails is considered not medically reasonable and necessary. “….”matrixectomy may be considered medically reasonable and necessary for the treatment of a symptomatic ingrown toenail or fingernail.”

COMMENT#1 Frequency is inappropriately assigned for the reasons we discussed above, regarding no coverage for more frequent surgical treatments.

COMMENT#2 Remove the word "symptomatic", since this can apply to asymptomatic ingrown nails as well, especially for neuropathic patients.

1. Total vs Partial. Somewhere in this LCD the concept of “partial” is being made equivalent to “Total”. CPT does not separate out CPT 11730 or 11750 from medial and lateral when partial procedure is performed. Unfortunately, there is no modifier to distinguish medial versus lateral of the same toe on a different date of service. A patient may present with a medial border ingrown nail, treated on this date of service but then requires the lateral border on a later date, it may be the exact same code and the exact same F or T modifier but clearly the medical record will show these procedures as being anatomically distinct. Using the time frames outlined in this proposed LCD and LCA immediately eliminates medically necessary covered care for a different anatomical border site if these time parameters are allowed. This in no way this should be a Medicare exclusion. It would be inappropriate for Novitas to limit different borders on the same finger or toe if done subsequently even within the next date of service if that possibly happened to be medically necessary. When discussing “permanent removal”, it would be nice if all procedures known to mankind had 100% effective results. After reviewing the Novitas/1st Coast LCD Benign Skin Lesions L34938, it makes no notation of not covering additional “excisions” if there is a regrowth of the lesion that was excised. After all, doesn’t the term “excision” imply that the lesion is now gone and should not grow back? Why apply “repeat” restrictions to CPT 11730 or CPT11750 that do not apply to other skin lesions that are permanent resolved by having an “excision”? Ingrown nails are a type “benign skin lesion”. We have 2 standards proposed by Novitas/First Coast. One thing that will be for certain is the skin lesions (benign) LCD will not be aligned and will have a separate standard for other skin lesions (ingrown nails) seems unreasonable.