Photodynamic Therapy

Policy Number:	**M20151110080**
Effective Date:	**1/1/2016**
Sponsoring Department:	**Health Care Services**
Impacted Department(s):	**Health Care Services**

Type of Policy: ☒ Internal ☒ External

Data Classification: ☐Confidential ☐Restricted ☒Public

Applies to (Line of Business):

☐ Corporate (All)
☒ State Products, if yes which plan(s): ☒MediSource; ☒ MediSource Connect; ☒Child Health Plus ☒Essential Plan
☒ Medicare, if yes, which plan(s): ☒MAPD; ☐PDP; ☒ISNP; ☒CSNP
☒ Commercial, if yes, which type: ☒Large Group; ☒Small Group; ☒Individual
☒ Self-Funded Services *(Refer to specific Summary Plan Descriptions (SPDs) to determine any pre-authorization or pre-certification requirements and coverage limitations. In the event of any conflict between this policy and the SPD of a Self-Funded Plan, the SPD shall supersede the policy.)*

Excluded Products within the Selected Lines of Business (LOB)

N/A

Applicable to Vendors? Yes ☐ No☒

Purpose and Applicability:

To set forth the medical necessity criteria for **photodynamic therapy (PDT).**

Policy:

Commercial, Self-Funded and Medicare Advantage:
PDT may be considered medically necessary and a covered benefit when any of the following criteria are met:

- Palliative esophageal and gastro-esophageal cancer;
- Non-Melanoma skin tumor;
- Readily accessible areas of the epidermis such as Bowen's disease, basal cell carcinoma, basal cell nevus syndrome and actinic keratoses on photo-damaged skin;
- Barrett's esophagus with high grade dysplasia;
- Esophageal superficial adenocarcinoma;
- Early-stage non-small lung cancer in members who are ineligible for surgery and radiation therapy.

Those receiving **Photofrin** during their course of PDT may receive a second course at a minimum of 30 days after initial therapy and up to 3 courses of PDT at 30-day time periods.

PDT of the skin is treated by either a blue light source (BLU-U 400 nm), to be used with the proprietary **aminolevulinic acid** (ALA) 20% solution (Levulan Kerastick) or a red light source (BF-RhodoLED 635 nm), to be used with the proprietary ALA 10% nanoemulsion (Ameluz).

Based upon assessment of peer-reviewed literature, photodynamic therapy has not been proven to be medically effective and is considered investigational in the treatment of other types of malignancies, including but not limited to:

- Colon
- Rectal
- Pancreas
- Hepatobiliary
- Prostate
- Bladder
- Brain
- Head and neck cancers and
- Barrett's esophagus (other than high grade dysplasia as stated above)

MediSource, MediSource Connect, Child Health Plus and Essential Plan:
MediSource, MediSource Connect, Child Health Plus and Essential Plan cover photodynamic therapy utilizing the criteria above.

Background:

Photodynamic therapy (PDT) is a two-step treatment in which a drug that acts as a photosensitizer is administered to specifically target a diseased tissue of interest, followed by illumination with visible light to activate the drug and destroy the target tissue. Photofrin (porfimer sodium) is the only photosensitizing agent with specific indications for use that has been approved by the U.S. Food and

Drug Administration (FDA). Photodynamic therapy limits damage to healthy cells because the photosensitizers tend to build up in abnormal cells and the light is focused directly on them.

An evaluation of the peer-reviewed scientific literature, including but not limited to subscription materials, has provided Independent Health the basis for its medical necessity coverage outlined above.

Pre-Authorization Required? Yes ☐ No ☒

Pre-authorization is not required at the present time. Criteria above will be utilized upon retro-review.

Definitions

Aminolevulinic acid is a photosensitizer that when exposed to light of appropriate wavelength and energy, produces a photodynamic reaction resulting in local cytotoxicity. Precancerous and cancerous cells exhibit a higher rate of porphyrin induction compared to normal cells. The gel form, Ameluz, is lesion-directed and field-directed topical treatment of mild to moderate actinic keratosis of the face and scalp; to be used in conjunction with photodynamic therapy with narrowband red-light illumination (using BF-RhodoLED lamp). The solution form Levulan Kerastick is topical treatment of minimally to moderately thick actinic keratoses of the face or scalp; to be used in conjunction with photodynamic therapy with blue light illumination (using BLU-U blue light).

Photodynamic therapy (PDT) for the treatment of precancerous lesions involves the selective destruction of abnormal cells through light activation of a photosensitizer in the presence of oxygen with the advantage compared with other treatments is the fact that it can be selectively applied, thus sparing the surrounding tissue from iatrogenic damage.

Photofrin, porfimer sodium, is a photosensitizer which is activated by red light from a laser. It is FDA approved to treat patients with cancer of the esophagus, Barrett's esophagus with dysplasia and a type of non-small cell lung cancer. The major possible side effects from porfimer sodium are photosensitivity reactions (reactions triggered by light) and swelling in the treated area.

References

Related Policies, Processes and Other Documents

N/A

Non-Regulatory references

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Regulatory References

Centers for Medicare and Medicaid (CMS) [web site]. National Coverage Determination (NCD) for Treatment of Actinic Keratosis (250.4). Available at: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=129&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Upstate&KeyWord=actinic&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAABAAAAAAAA%3d%3d& Accessed April 24, 2024.

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This policy contains medical necessity criteria that apply for this service. Please note that payment for covered services is subject to eligibility criteria, contract exclusions and the limitations noted in the member's contract at the time the services are rendered.

Version Control

Signature / Approval on File? Yes ☒ No☐

Revision Date	Owner	Notes
7/1/2024	Health Care Services	Reviewed
1/1/2024	Health Care Services	Revised
7/1/2023	Health Care Services	Reviewed
7/1/2022	Health Care Services	Reviewed
8/1/2021	Health Care Services	Revised
12/1/2020	Health Care Services	Reviewed
1/1/2020	Medical Management	Reviewed
1/1/2019	Medical Management	Revised
2/1/2018	Medical Management	Revised
11/1/2017	Medical Management	Revised
12/1/2016	Medical Management	Revised