## Experimental/Investigational/Unproven Policies

Ten healthcare carriers; evaluated March 5 2020.

Below I reviewed ten Experimental/Investigational (E/I) healthcare policies. The goal here is to compare and contrast them. While very similar, there are differences in the definitions, requirements, and restrictions. I have **emphasized** issues and terms I consider important. Remember my mottos:

* *Words* matter
* *Specificity* matters
* *Dates* matter
* *Accuracy* matters

Tailoring your pre-authorization packet, documentation, and letters to the carrier’s policy requirements and *verbiage* is the very best strategy to obtain pre-authorization and win an appeal if denied. At the end of this document is a cut-and-paste list of verbiage to include generously in your pre-authorization and appeal documents.

**Experimental / Investigational / Unproven Policies**

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| --- | --- | --- |
| 1 | Anthem Blue Cross Blue Shield (lipo for lipedema approved) | 11/1/2019 |
| 2 | Allways health insurance (lipo for lipedema specifically excluded) | 3/1/2020 |
| 3 | BCBS-ND (lipo for lipedema not referenced) | Jan 1 2020 |
| 4 | BCBS-VT (lipo for lipedema not referenced) | 5/1/2018 |
| 5 | Fallon Health (lipo for lipedema not referenced) | 9/1/2019 |
| 6 | HealthNet (lipo for lipedema not referenced) | 1/1/2020 |
| 7 | Meridian Health Plan (lipo for lipedema not referenced) | 11/1/2015 |
| 8 | Molina Healthcare (lipo for lipedema not referenced) | 6/25/2014 |
| 9 | Ventura County Health Plan (lipo for lipedema not referenced) | 2/14/2019 |
| 10 | Wellmark-BC-BS (lipo for lipedema not referenced) | 2/6/2020 |

**Anthem Blue Cross Blue Shield** has a published E/I policy (2015) and a more current policy NC00009, *Cosmetic and Reconstructive Services* accepting liposuction for lipedema as reconstructive and medically necessary. It was effective 11/1/2019.

All policy decisions are at the discretion of the medical director.

The Anthem policy from 2015 (outdated) includes a list of E/I **research quality and efficacy flaws**.

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**Allways Health Insurance** provides coverage when the surgery or procedure is reconstructive in nature, i.e. needed to improve the functioning of a body part, treat an associated medical complication, or is otherwise medically necessary, even if the surgery or procedure may also improve or change the appearance of a portion of the body. Policy Date: 3/1/2020.

Note: InterQual® Criteria Lookup link [used to determine if panniculectomy is warranted.]

Note: Liposuction is often an integral part the surgical removal of excessive skin [panniculectomy ]; this is not separately reimbursed.

[Excluded are] Any procedure where the primary purpose is to **enhance aesthetics**, including but not limited to: …**liposuction.**

**General Exclusion**: 4. **Liposuction for lipedema** [this is specifically excluded].

March 2020: Annual review. *Added exclusion Liposuction for lipedema*. References updated.

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**BCBS-ND** Experimental / Investigational Revised Jan 1 2020

Experimental/Investigational services are defined as a treatment, procedure, facility, equipment, drug, service or supply (“intervention”) that has been determined not to be **medically effective** for the condition being treated.

Charges submitted for the services listed in this policy are denied as experimental / investigational. The determination for denial is based on ANY of the following reasons:

1. The intervention does not have Food and Drug Administration (FDA) approval to be marketed for the specific relevant indication(s).
2. Available scientific evidence does not permit **conclusions c**oncerning **the effect of the intervention on health outcomes.**
3. The intervention is not proven to be as **safe or effective** in achieving an outcome equal to or **exceeding the outcome of alternative therapies.**
4. The intervention does not improve health outcomes.

The intervention is not proven to be **applicable** **outside the research setting**. [Not applicable to the general population; find research supporting this].

The policy includes a long list of CPT™ codes but the liposuction CPT™ codes were not listed.

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**BCBS-VT** Experimental / Investigational; makes point that the **diagnosis code** will cause the denial. Policy Date: 5/1/2018.

“Experimental of Investigational Services” means health care items or services that are either **not generally accepted** by informed health care providers **in the United States** [perhaps omitting foreign research common in lipedema? - Jeff] as effective in treating the condition, illness or diagnosis for which their use is proposed, or are not proven by medical or scientific evidence to be effective in treating the condition, illness or diagnosis for which their use is proposed.

The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.

The evidence should consist of **well-designed** and **well-conducted investigations** published in **peer-reviewed** journals. The **quality** of the body of studies and the **consistency** of the results are considered in evaluating the evidence.

The evidence should demonstrate that the technology can **measure** or **alter the physiological changes** related to a disease, injury, illness, or condition. In addition, there should be evidence or a convincing argument based on established medical facts that such measurement or alteration affects health outcomes.

The BCBS-VT policy is 87 pages and a pretty good overview; it is mostly a long list of complete CPT codes**. Liposuction not addressed** or found in the E/I/U policy document.

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**Fallon Health** excludes coverage of experimental/investigational procedures due to their lack of reliable or detailed clinical evidence of **superior clinical outcomes**. Fallon Health evaluates many different types of clinical evidence in determining if a procedure or treatment has a **greater safety or efficacy** **than conventional treatments**. This is inclusive but not limited to published technological assessments, randomized control studies, published peer literature, and expert opinions.

Fallon Health will evaluate available, peer-reviewed scientific literature in relation to an overall clinical outcome and it’s acceptance of use in a clinical setting. **Prior authorization is required** for the use of any service or procedure as outlined in this policy. These requests must be supported by the treating provider(s) medical records. Policy Date: 9/1/2019.

In your appeal, **reference experts in the field of lipedema and LS-TL**.

I would first look at the FEB 2020 liposuction for lipedema outcomes research paper and the list of researchers. There is no reference to liposuction or lipedema for their liposuction or their CPT codes in the policy.

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**HealthNet** E/I/U Policy 1/1/2020; some Medicaid policies.

Health Net considers as Experimental or Investigational if it meets any of the following:

1. It is **currently the subject of active and credible evaluation** (e.g., clinical trials or research) to determine: clinical efficacy, therapeutic value or beneficial effects on health outcomes, or benefits beyond any established medical based alternative. [this verbiage suggests to me that they could deny any procedure currently being evaluated - Jeff]
2. FDA approval.
3. The most recent peer-reviewed scientific studies published or accepted for publication by **nationally recognized medical journals** do not conclude, or are inconclusive in finding, that the Service is **safe and effective** for the treatment if the condition for which authorization of the Service is requested. safe / effective

Liposuction is not addressed or found in the policy document.

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**Meridian Health Plan**

E/I/U is any procedure, device or pharmaceutical agent that is **still undergoing pre-clinical or clinical evaluation [could deny anything - Jeff]**, and/or has not yet received regulatory approval. It is the use of a service, procedure or supply that is not recognized by the Plan as **standard medical care** for the condition, disease, illness or injury being treated. A service, procedure or supply includes but is not limited to the diagnostic service, treatment, facility, equipment, drug or device. When basic safety and efficacy have been demonstrated by the experimental scientific process, the investigational phase begins. Policy Date: 11/1/2015

Adequate evidence is defined as at **least two documents** of medical and scientific evidence that indicate that the proposed treatment is likely to be beneficial to the member adequate evidence

The Meridian Health Plan is particularly detailed. I copied it to a separate word document.

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**Molina Healthcare Experimental / Investigational Policy:** no reference to any specific CPT codes or procedures; Policy Date: 6/25/2014 (outdated)

“Excluded…are procedures…that have not successfully completed a Phase III trial“

Molina Healthcare Molina Healthcare defines the terms “experimental” or “investigational” or “unproven” (E/I/U) as the use of a technology drug, device, treatment or procedure that has not been recognized as having **proven benefit** in clinical medicine for any condition, illness, disease or injury being treated

Molina Healthcare has **five criteria**:

1. FDA approval
2. Published peer-reviewed literature must demonstrate the **proven beneficial impact** of the service/procedure on health outcomes for the given indication.
3. Published **peer-reviewed literature** must demonstrate that the technology must be at least as effective as established technology for the given indication.
4. Published peer-reviewed literature must demonstrate evidence that the technology improves health outcomes over time for the given indication.
5. The outcomes for the given indication must be obtainable outside investigational settings within the medical community.

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**United Healthcare/Oxford Health Experimental / Investigational Policy**

This is for *Medicare coverage of clinical trials*; Policy Date: 1/1/2018

Remember that federal or state mandates trump carrier policies. Individual plans vary. Oxford has plans in different states.

Oxford recognizes that **peer-reviewed** documents in scientific and medical literature may establish that an experimental and/or investigational treatment or procedure **may be better than** the standard treatments available to treat a member’s life threatening or disabling condition and/or disease. [Way this reads is more lenient than others; more leeway to appeal and argue your case - Jeff].

Oxford has determined that it will create a limited exception to the exclusion of experimental and investigational treatments and provide coverage for in-network experimental and investigational procedures that meet the criteria set forth in this policy. Such coverage is subject to the member’s other benefits and exclusions. Oxford’s determination of whether the criteria have been met will be based upon the opinion of an independent consultant/peer reviewer with expertise in the area of practice appropriate to treat the member’s condition or disease.

Exception: For New York Plans, the member's condition and/or disease is not required to be life threatening or disabling.

United Healthcare/Oxford Health Under no circumstances will this policy extend coverage to **unproven therapies**. [United Healthcare is the only carrier I’ve found so far that provides a separate definition of “unproven.” - Jeff]

**Unproven therapies** are treatments or procedures that lack significant medical documentation to support their medical effectiveness. Oxford does not provide coverage for any treatment modality that has not been proven medically effective or is not generally recognized as effective or appropriate for the particular diagnosis or treatment of the member’s particular condition.

Documentation Requirements: The member’s **medical record**, in conjunction with at least **two (2) published peer-reviewed documents** from the available scientific and medical evidence and any other pertinent information supplied, must establish that the proposed experimental or investigational treatment is likely to be more beneficial that any standard treatment(s) for the member’s life-threatening or disabling condition or disease.\*

The UH policy is long and very detailed; recommend reading for the ambitious.

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**Ventura County Health Plan Experimental / Investigational** Policy Date: 2/14/2019

Approval for E/I/U procedures must be consistent with §1370.4 of the Knox Keene Act, experimental or investigational procedures:

Life-threatening condition; standard treatment unsuccessful, ineffective and proposed treatment likely to be effective; treatment is "promising."

A **promising treatment** is one that has shown effectiveness as supported in credible peer reviewed literature or by the credible medical opinion of independent medical experts in the relevant specialty, designated by VCHCP. [First instance of “promising treatment” defined - Jeff]

This policy outlines how to get an **E/I/U treatment approved**; it is not how to avoid the designation, it is how to **get an exception** to a procedure that is listed as not covered..

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**Wellmark BC-BS** is in Iowa and South Dakota. It is dominant in Iowa. It is an independent licensee.

The terms "unproven, experimental or investigational" are generically defined as: A supply, procedure, therapy or device whose **effectiveness has not been demonstrated** by required scientific evidence and properly authorized by governing entities in order to be acknowledged as medically effective for the improvement of function for specific conditions or treatment. Policy Date: 2/6/2020

A treatment is considered investigational or experimental when it has progressed to limited human application, but has not **achieved recognition** as being **proven effective** in clinical medicine. 2/6/2020

To determine investigational or experimental status, we may refer to the technical criteria established by the Blue Cross and Blue Shield Association, including whether a service, supply, device, or drug meets these criteria:

It has final approval from the appropriate governmental regulatory bodies. FDA approved

1. The scientific evidence must permit conclusions concerning its effect on health outcomes. conclusions are overwhelming and consistent
2. It improves the net health outcome. focus on net health outcomes
3. It’s as beneficial as any established alternatives. no other alternatives
4. The health improvement is attainable outside the investigational setting. outside setting

**General E/I/U Information**

The national Blue Cross and Blue Shield Association has a Medical Advisory Panel responsible for setting policy on what is Experimental / Investigational / Unproven.

State boards also weigh in on what is considered experimental, investigational, unproven or allowed. A good example from Eyecare is that optometrists are specific set of procedures but it varies by state Optometry board.

Use **quantitative scores** whenever possible (e.g., decrease of pain, increase of mobility, six minute walk evaluation, risk of fall).

Some carriers define **defect** as: pain or other physical deficit that interferes with activities of daily living or impaired physical activity.

## Keyword / Verbiage List

**General Notes**

Avoid "enhance aesthetics" or any verbiage considered cosmetic; confirm this with all your Providers and their office visit documentation.

Always include at least **two documents** of medical and scientific evidence [to support claim] (two policies indicated two)

“excluded…are procedures…that have not successfully completed a phase III trial“ [Molina healthcare].

One policy specifically referenced “United States research” which would omit a lot of foreign research on liposuction and lipedema.

**Unproven therapies** are treatments or procedures that lack significant medical documentation to support their medical effectiveness

Concerning getting an exemption to an E/I policy denial, often if the condition or disease is **life threatening or disabling** then the patient can appeal on that basis. Policies vary on this and there may be state regulations concerning life-threatening exemptions.

I/E are treatments that are currently the subject of active and credible evaluation (e.g., clinical trials or research) to determine: clinical efficacy, therapeutic value or beneficial effects on health outcomes [Healthnet - I consider this a rather strict interpretation]

Considered I/E...treatment progressed to limited human application, but has not achieved recognition as being proven effective in clinical medicine. [Wellmark]

**Use quantitative scores** whenever possible (e.g., decrease of pain, increase of mobility, six minute walk evaluation, risk of fall).

Some carriers define **defect** as: pain or other physical deficit that interferes with activities of daily living or impaired physical activity.

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**Include the following terms, phrasing and supporting research** in your pre-authorization or appeal documentation package (cut-and-paste):

Medically effective

FDA approval of equipment

Conclusions...the effect of the intervention on health outcomes

Make argument …that measurement(s) or alteration affects health outcomes

Safe or effective

Exceeding the outcome of alternative therapies

Improve health outcomes

Applicable outside the research setting

The specific diagnosis of lipedema warrants approval.

Well-designed research

Well-conducted investigations

Nationally-recognized medical journals

Published in peer-reviewed journals

Quality of the body of studies and the consistency of the results

Superior clinical outcomes [Fallon health; use of "superior"]

Greater safety or efficacy than conventional treatments

Technological assessments

Randomized control studies

Published peer literature

Expert opinions

Recognized by the plan as standard medical care for the disease being treated

Peer-reviewed literature

Proven beneficial impact