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**2025 Blue Cross and Blue Shield Service Benefit Plan - FEP Blue Focus**

**Section 10. Definitions of Terms We Use in This Brochure**

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2. Medically necessary;
3. Primarily and customarily used only for a medical purpose;
4. Generally useful only to a person with an illness or injury;
5. Designed for prolonged use; and
6. Used to serve a specific therapeutic purpose in the treatment of an illness or injury.

**Experimental or investigational services**

Experimental or investigational shall mean:

1. A drug, device, or biological product that cannot be lawfully marketed without approval of the U.S. Food and Drug Administration (U.S. FDA); and approval for marketing has not been given at the time it is furnished; or
2. Reliable evidence shows that the healthcare service (e.g., procedure, treatment, supply, device, equipment, drug, biological product) is the subject of ongoing phase I, II, or III clinical trials or under study to determine its maximum tolerated dose, its toxicity, its safety, its efficacy, or its efficacy as compared with the standard means of treatment or diagnosis; or
3. Reliable evidence shows that the consensus of opinion among experts regarding the healthcare service (e.g., procedure, treatment, supply, device, equipment, drug, biological product) is that further studies or clinical trials are necessary to determine its maximum tolerated dose, its toxicity, its safety, its efficacy, or its efficacy as compared with the standard means of treatment or diagnosis; or
4. Reliable evidence shows that the healthcare service (e.g., procedure, treatment, supply, device, equipment, drug, biological product) does not improve net health outcome, is not as beneficial as any established alternatives, or does not produce improvement outside of the research setting.

Reliable evidence shall mean only evidence published in peer-reviewed medical literature generally recognized by the relevant medical community and physician specialty society recommendations, such as:

1. Published reports and articles in the authoritative medical and scientific literature;
2. The written protocol or protocols used by the treating facility or the protocol(s) of another facility studying substantially the same drug, device, or biological product or medical treatment or procedure; or
3. The written informed consent used by the treating facility or by another facility studying substantially the same drug, device, or biological product or medical treatment or procedure.

### **Generic alternative**

A generic alternative is a U.S. FDA-approved generic drug in the same class or group of drugs as your brand-name drug. The therapeutic effect and safety profile of a generic alternative are similar to your brand-name drug, but it has a different active ingredient.

### **Generic equivalent**

A generic equivalent is a drug whose active ingredients are identical in chemical composition to those of its brand-name counterpart. Inactive ingredients may not be the same. A generic drug is considered “equivalent,” if it has been approved by the U.S. FDA as interchangeable with your brand-name drug.

### **Group health coverage**

Healthcare coverage that you are eligible for based on your employment, or your membership in or connection with a particular organization or group, that provides payment for medical services or supplies, or that pays a specific amount of more than \$200 per day for hospitalization (including extension of any of these benefits through COBRA).

### **Healthcare professional**

A physician or other healthcare professional licensed, accredited, or certified to perform specified health services consistent with state law. See Section 3 for information about how we determine which healthcare professionals are covered under this Plan.

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