

Reimbursement Clinical Guidelines: Experimental and Investigational Procedures Reimbursement Policy

Policy Position

This policy describes the circumstances under which a service is considered experimental/investigational for **all indications**. A service is considered experimental, investigative, or unproven if reliable evidence shows that the treatment is “under study to determine its safety, efficacy, toxicity, maximum tolerated dose, or its efficacy as compared with a standard means of treatment or diagnosis”. FirstCare Health Plans restricts coverage to those devices, treatments, or procedures for which the safety and efficacy have been proven, or where the clinical evidence is such that the treatment is at least as beneficial as any established evidence-based alternatives. Any device, medical treatment, supply or procedure for which safety and efficacy has not been established and proven is considered investigational (unproven) and therefore not medically necessary and is excluded from coverage. Claims submitted for these services are denied as not a covered benefit. The Complaints and Appeals process are described in the Provider Manual¹. This policy is applicable to Commercial and Marketplace benefit products administered by FirstCare Health Plans. Medicaid, CHIP, and Medicare will follow the state procedure manuals and Centers for Medicare and Medicaid Services’ local and national coverage documents.

Note: Contracts exclude from coverage, among other things, services, or procedures that are considered investigational. Providers may bill members for services or procedures that are considered investigational. Providers are encouraged to inform members before rendering such services that the members are financially responsible for the cost of these services.

Disclaimer

FirstCare has developed coding and reimbursement policies (“Reimbursement Policies”) to provide ready access and general guidance on reimbursement methodologies for medical, surgical and behavioral health services. These policies are subject to all terms of the Provider Service Agreement as well as changes, updates and other requirements of Reimbursement Policies. All Reimbursement Policies are also subject to federal HIPAA rules, and in the case of medical code sets (HCPCS, CPT, ICD-10), FirstCare accepts codes valid for the date of service. Additionally, Reimbursement Policies supplement certain standard FirstCare benefit plans and aid in administering benefits. Thus, federal and state law, contract language, etc. take precedence over the Reimbursement Policies (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). Moreover, the terms of a member’s particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from Reimbursement Policies. For example, a member’s benefit plan may contain specific exclusions related to the topic addressed in Reimbursement Policies.

Most importantly, our Reimbursement Policies relate exclusively to the administration of health benefit plans and are **not** recommendations for treatment or treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. Providers and their office staff must use self-service channels to verify effective dates and copayments for commercial members prior to initiating services. Copayments, deductible, and/or coinsurance may apply depending upon the member’s benefit plan specific. All Reimbursement Policies are subject to change prior to the annual review date. Lines of business (LOB) are subject to change without notice; individual Reimbursement Policies list the applicable LOBs.

Reimbursement Guidelines

Any device, medical treatment, supply or procedure for which safety and efficacy has not been established and proven is considered investigational (unproven) and therefore not medically necessary and is excluded from coverage. A service or supply, including, but not limited to, a drug, treatment, device, or procedure is considered experimental or investigational if any of the following criteria are met:

HEALTH PLANS

- It cannot be lawfully marketed without the approval of the Food and Drug Administration (FDA) and final approval is not granted at the time of its use or proposed use
- It is the subject of a current investigational new drug or new device application on file with the FDA
- The predominant opinion among experts as expressed in medical literature is that usage should be largely confined to research settings
- The predominant opinion among experts as expressed in medical literature is that further research is needed in order to define safety, toxicity, effectiveness or effectiveness compared with other approved alternatives
- It is not investigational in itself, but would not be medically necessary except for its use with a drug, device, treatment, or procedure that is investigational or experimental.

When determining whether a drug, treatment, device, or procedure is experimental or investigational, the following information may be considered:

- The member's medical record
- The protocol(s) pursuant to which the treatment is to be delivered
- Any consent document the patient has signed or will be asked to sign, in order to undergo the procedure
- The referenced medical or scientific literature regarding the procedure at issue as applied to the injury or illness at issue
- Regulations and other official actions and publications issued by the federal government
- The opinion of a third party medical expert in the field, obtained by FirstCare, with respect to whether a treatment or procedure is experimental or investigational

Codes and Modifiers

We encourage all of our providers utilize the FirstCare Self-Service Provider Portal, <http://firstcare.com/en/Providers>. Register today! Go to the login page at <https://my.firstcare.com/Web> and select the "Create an account today!" link or "Create an Account button and choose "Provider" from the popup selector. Note: If you already have access to the Provider Portal and need to add new users, simply follow the same steps above once logged into your account at View/Edit My Info and Registered Providers.

To view a code considered experimental and investigational for all indications, go to the login page at <https://my.firstcare.com/Web> and use the Authorization Code Search.

Note: For other service codes that are experimental for **some indications**, not all, an authorization may be required.

Related Policies and References

1. Complaints and Appeals Procedures. Retrieved from <http://www.firstcare.com/Providers>
2. Peer Literature Review. (n.d.). Policy Reporter. Retrieved from <https://portal.policyreporter.com/login>