

SECTION 4: EXCLUSIONS AND LIMITATIONS

4.1 General Exclusions

This Policy provides comprehensive health coverage for Covered Persons as defined in Section 2, subject to the exclusions, limitations, and conditions set forth herein. The Company shall not be liable for charges incurred for services, treatments, supplies, or procedures that fall outside the scope of covered benefits as defined in this Section.

4.2 Experimental, Investigative, and Unproven Services

Coverage is limited to those services, treatments, and supplies that are medically necessary, provided they are not considered experimental, investigative, or unproven by generally accepted medical standards. For purposes of this Policy, a service, treatment, device, or supply shall be deemed experimental, investigative, or unproven if:

- (a) It has not received final approval from the appropriate governmental regulatory body, including but not limited to the Food and Drug Administration (FDA), for the specific indication or use for which it is prescribed or recommended;
- (b) Reliable evidence, as determined by the Company's medical review board and based on peer-reviewed medical literature, does not demonstrate that the service or treatment is as safe and effective as standard treatments for the condition in question;
- (c) It is the subject of ongoing Phase I, Phase II, or Phase III clinical trials, or is otherwise under investigation to determine its maximum tolerated dose, toxicity, safety, efficacy, or comparative efficacy versus standard treatment;
- (d) Authoritative medical and scientific evidence, including but not limited to technology assessments by organizations such as the Blue Cross Blue Shield Association Technology Evaluation Center (TEC), ECRI Institute, Hayes Inc., or similar entities, does not permit conclusions concerning the effect of the service or treatment on health outcomes.

4.3 Application of Medical Necessity Standards

All determinations regarding whether a service is experimental, investigative, or unproven shall be made by the Company's Medical Director or designated medical review personnel, based on objective clinical evidence and in accordance with nationally recognized clinical guidelines. The Company reserves the right to require prior authorization for any service that may be subject to this exclusion. The fact that a physician or other healthcare provider has prescribed, recommended, or approved a service does not, in itself, establish that the service is medically necessary or covered under this Policy.

4.4 Additional Exclusions

In addition to the foregoing, the following services and supplies are specifically excluded from coverage under this Policy: cosmetic procedures not medically necessary for functional restoration; services provided by family members residing in the Covered Person's household; charges in excess of Usual, Customary, and Reasonable (UCR) rates as determined by the Company; and services for which the Covered Person has no legal obligation to pay or for which no charge would be made in the absence of insurance coverage.