

## SHCP for Active Duty

|  |   |  |
|--|---|--|
| <p><b>1. Has the provider been suspended or sanctioned by TRICARE?</b></p>   | <p><input type="checkbox"/> <b>Yes</b><br/>Coverage not authorized.<br/>No waiver is possible.</p>  | <p><input type="checkbox"/> <b>No</b><br/>Please proceed to Question 2</p>   |
| <p><b>2. Is the requested care prohibited by policy?</b><br/>Services prohibited by policy include:<br/>- Chiropractic care – HA Policy 03-021<br/>- Bariatric surgery – HA Policy 07-006</p>  | <p><input type="checkbox"/> <b>Yes</b><br/>Coverage not authorized.<br/>Waiverable at the Director,<br/>TMA level.*</p>   | <p><input type="checkbox"/> <b>No</b><br/>Please proceed to Question 3</p>   |
| <p><b>3. Is the requested care part of the TRICARE benefit?</b></p>  | <p><input type="checkbox"/> <b>Yes</b><br/>Coverage is authorized.<br/>Access standards pertain.</p>  | <p><input type="checkbox"/> <b>No</b><br/>Please proceed to Question 4</p>   |
| <p><b>4. Is the requested care medical or dental care?</b><br/>The SHCP authorizes purchase of medical and/or dental care for active duty members. If the service being considered is not medical or dental care (e.g., sit-ski for a paraplegic; sperm banking), then SHCP may not be used – 10 USC 1074(c)(1)</p>  | <p><input type="checkbox"/> <b>Yes</b><br/>Please proceed to Question 5</p>   | <p><input type="checkbox"/> <b>No</b><br/>Coverage not authorized.<br/>No waiver is possible.</p>                      |
| <p><b>5. Is the requested care prohibited by statute?</b><br/>Services explicitly prohibited by statute include:<br/>- Abortion (except when the life of the mother would be endangered if the fetus were carried to term) – 10 USC 1093 (a) prohibits use of DHP funds for elective abortion.<br/>- Research involving human subjects (unless the requirements of 32 CFR 219 have been satisfied) – 42 USC 300v-1(b)</p>  | <p><input type="checkbox"/> <b>Yes</b><br/>Coverage not authorized.<br/>No waiver is possible.</p>  | <p><input type="checkbox"/> <b>No</b><br/>Please proceed to Question 6</p>   |
| <p><b>6. Are active duty members prohibited by regulation from receiving the requested care?</b><br/>Active duty are not necessarily precluded from obtaining healthcare services that are excluded from the TRICARE benefit by regulation, but the CFR does prohibit services that are not necessary to assure adequate availability of health care services. Examples include:<br/>- IVF, other non-coital reproductive technologies<br/>- Elective (not medically necessary) circumcision<br/>- Reversal of elective sterilization procedure<br/>- Cosmetic surgery (but “correction of minor dermatological blemishes and minor anatomical anomalies” is permitted)</p>  | <p><input type="checkbox"/> <b>Yes</b><br/>Private elective coverage is prohibited by statute.<br/>Coverage not authorized nor waiverable at the Director,<br/>TMA level.</p> | <p><input type="checkbox"/> <b>No</b><br/>Please proceed to Question 7</p>   |
| <p><b>7. Is the requested care proven safe and effective?</b><br/>As a general rule, the SHCP may be used only to procure care that is safe and effective. Phase II and III clinical trials under the DoD/NCI Cancer Clinical Trials Demonstration may be approved under SHCP, on a case by case basis.<br/>Examples of care that may not be approved under SHCP:<br/>- Phase II and III clinical trials outside the TRICARE benefit<br/>- Compassionate use devices outside the TRICARE benefit<br/>- Drug or device that has not yet received pre-market approval from the FDA<br/>- Phase I clinical trial<br/>- Care available only outside the United States<br/>[Member retains appeal rights when the MTF commander or MMSO determines care is not safe and effective; care found on appeal to be safe and effective may be approved for SHCP.]</p> | <p><input type="checkbox"/> <b>Yes</b><br/>Please proceed to Question 8</p>   | <p><input type="checkbox"/> <b>No</b><br/>Coverage not authorized.<br/>Waiverable at the Director,<br/>TMA level.*</p> |
| <p><b>8. Is the requested care necessary to assure adequate availability of health care services to the member?</b></p>  | <p><input type="checkbox"/> <b>Yes</b><br/>Coverage is authorized.<br/>Access standards pertain.</p>  | <p><input type="checkbox"/> <b>No</b><br/>Coverage not authorized.<br/>Waiverable at the Director,<br/>TMA level.*</p> |

\*Upon the request of an authorized official of the uniformed service concerned, to ensure adequate availability of health care services to the ADSM. Applicable only under very unusual and limited circumstances.

## **Determining Whether Care is Proven or Unproven Care**

In order to ensure that our beneficiaries receive services that meet the standard of care, that is, appropriate medical care, the Code of Federal Regulations (32 CFR 199.4(g)(15)) requires that there be reliable evidence, as that term is defined in 32 CFR 199.2(b), showing that any medical treatment or procedure has been the subject of well controlled studies of clinically meaningful endpoints that demonstrate safety and efficacy compared with the standard means of treatment or diagnoses.

The definition of reliable evidence in 32 CFR 199.2(b) (which is also included in Chapter 1, Section 2.1 of the TRICARE Policy Manual (August 2002 edition)) provides the TRICARE hierarchy of reliable evidence used to determine whether a drug, device, medical treatment or procedure has moved from the status of unproven to the position of nationally accepted medical practice as follows:

1. Well-controlled studies of clinically meaningful endpoints, published in refereed medical literature
2. Published formal technology assessments
3. Published reports of national professional medical associations
4. Published national medical policy organization positions
5. Published reports of national expert opinion organizations.

Specifically not included in the meaning of reliable evidence are reports, articles, or statements by providers or groups of providers containing only abstracts, anecdotal evidence, or personal professional opinions. Also not included in the meaning of reliable evidence is the fact that a provider or number of providers have elected to adopt a drug, device, or medical treatment or procedures as their personal treatment or procedure of choice or standard of practice.

In the case of rare diseases, TRICARE recognizes that meeting the usual high standard of evidence may not be possible due to the small numbers of patients available to participate in studies. For rare diseases, a slightly less rigorous level of evidence can be accepted as significant support for use of a treatment on a case-by-case basis. Even for rare diseases, however, 32 CFR 199.4(g)(15)(ii) requires that we determine that a proposed treatment is safe and effective for that disease. The sources that may be consulted to determine if proposed therapy is considered safe and effective are:

1. Trials published in refereed medical literature
2. Formal technology assessments
3. National medical policy organization positions
4. National professional associations
5. National expert opinion organizations

## SHCP for Non Active Duty

|  |   |  |
|--|---|--|
| <p><b>1. Is the beneficiary an inpatient AND still under the care of a military treatment facility provider (i.e., has not been disengaged)?</b></p> <p>The SHCP authorizes purchase of medical care for non-active duty members only when ordered by an MTF provider for an MTF inpatient for whom the MTF provider maintains responsibility.</p>   | <p><input type="checkbox"/> <b>Yes</b><br/>Please proceed to Question 2</p>   | <p><input type="checkbox"/> <b>No</b><br/>Coverage not authorized.<br/>No waiver is possible.</p>  |
| <p><b>2. Is the provider a TRICARE-certified provider?</b></p>   | <p><input type="checkbox"/> <b>Yes</b><br/>Please proceed to Question 3</p>   | <p><input type="checkbox"/> <b>No</b><br/>Coverage not authorized.<br/>No waiver is possible.</p>  |
| <p><b>3. Is the requested care part of the TRICARE benefit?</b></p>  | <p><input type="checkbox"/> <b>Yes</b><br/>Coverage is authorized.<br/>Access standards pertain.</p>                | <p><input type="checkbox"/> <b>No</b><br/>Please proceed to Question 4</p>   |
| <p><b>4. Is the requested care medical care?</b></p> <p>The SHCP authorizes purchase of medical care for non-active duty members. If the service being considered is not medical care (e.g., cord blood banking; home whirlpool), then SHCP may not be used.</p>   | <p><input type="checkbox"/> <b>Yes</b><br/>Please proceed to Question 5</p>   | <p><input type="checkbox"/> <b>No</b><br/>Coverage not authorized.<br/>No waiver is possible.</p>  |
| <p><b>5. Is the requested care prohibited by statute?</b></p> <p>Services explicitly prohibited by statute include:</p> <ul style="list-style-type: none"> <li>- Abortion (except when the life of the mother would be endangered if the fetus were carried to term) – 10 USC 1093(a) prohibits use of DHP funds for elective abortion.</li> <li>- Research involving human subjects (unless the req'ts of 32 CFR 219 have been satisfied) – 42 USC 300v-1(b)</li> <li>- Cosmetic surgery – 10 USC 1079(a)(12)</li> <li>- Care provided by a non-certified TRICARE institutional provider – 10 USC 1079(j)(3)</li> </ul> | <p><input type="checkbox"/> <b>Yes</b><br/>Coverage not authorized.<br/>No waiver is possible.</p>                  | <p><input type="checkbox"/> <b>No</b><br/>Please proceed to Question 6</p>   |
| <p><b>6. Is the requested care prohibited by regulation?</b></p> <p>Examples of services prohibited by regulation include:</p> <ul style="list-style-type: none"> <li>- Care provided by a non-certified TRICARE individual provider – 32 CFR 199.4(b) and 199.4(c)</li> <li>- Care related to complications of non-covered surgery – 32 CFR 199.4(e)(9)</li> </ul>  | <p><input type="checkbox"/> <b>Yes</b><br/>Coverage not authorized.<br/>Waiverable at the Director, TMA level.*</p> | <p><input type="checkbox"/> <b>No</b><br/>Please proceed to Question 7</p>   |
| <p><b>7. Is the requested care medically necessary?</b></p>  | <p><input type="checkbox"/> <b>Yes</b><br/>Please proceed to Question 8</p>   | <p><input type="checkbox"/> <b>No</b><br/>Coverage not authorized.<br/>No waiver is possible.</p>  |
| <p><b>8. Is the requested care proven safe and effective?</b></p> <p>Examples of services currently not considered proven safe and effective under TRICARE include:</p> <ul style="list-style-type: none"> <li>- Phase I clinical trial</li> <li>- Phase II and III clinical trials outside the TRICARE benefit</li> <li>- Compassionate use devices outside the TRICARE benefit</li> <li>- Drug or device that has not yet received pre-market approval from the FDA</li> </ul>   | <p><input type="checkbox"/> <b>Yes</b><br/>Please proceed to Question 9</p>   | <p><input type="checkbox"/> <b>No</b><br/>Coverage not authorized.<br/>No waiver is possible.</p>  |
| <p><b>9. Is the requested care prohibited by policy?</b></p> <p>Examples of services explicitly prohibited by policy include:</p> <ul style="list-style-type: none"> <li>- FDA approved devices that are not part of the TRICARE benefit (e.g., cranial orthosis for positional plagiocephaly – TPM Chapter 8 Section 3.1; vagus nerve stimulator for refractory depression – TPM Chapter 4, Section 20.1)</li> </ul>  | <p><input type="checkbox"/> <b>Yes</b><br/>Coverage not authorized.<br/>Waiverable at the Director, TMA level.*</p> | <p><input type="checkbox"/> <b>No</b><br/>This is a case in which the TRICARE Policy Manual is silent on the service being requested. Coverage may be authorized at the discretion of the MTF Commander; access standards may or may not apply. The MCSC or TRO medical director can help determine the advisability of covering this service.</p> |

\* Applicable only under very unusual and limited circumstances.

## **Determining Whether Care is Proven or Unproven Care**

In order to ensure that our beneficiaries receive services that meet the standard of care, that is, appropriate medical care, the Code of Federal Regulations (32 CFR 199.4(g)(15)) requires that there be reliable evidence, as that term is defined in 32 CFR 199.2(b), showing that any medical treatment or procedure has been the subject of well controlled studies of clinically meaningful endpoints that demonstrate safety and efficacy compared with the standard means of treatment or diagnoses.

The definition of reliable evidence in 32 CFR 199.2(b) (which is also included in Chapter 1, Section 2.1 of the TRICARE Policy Manual (August 2002 edition)) provides the TRICARE hierarchy of reliable evidence used to determine whether a drug, device, medical treatment or procedure has moved from the status of unproven to the position of nationally accepted medical practice as follows:

1. Well-controlled studies of clinically meaningful endpoints, published in refereed medical literature
2. Published formal technology assessments
3. Published reports of national professional medical associations
4. Published national medical policy organization positions
5. Published reports of national expert opinion organizations.

Specifically not included in the meaning of reliable evidence are reports, articles, or statements by providers or groups of providers containing only abstracts, anecdotal evidence, or personal professional opinions. Also not included in the meaning of reliable evidence is the fact that a provider or number of providers have elected to adopt a drug, device, or medical treatment or procedures as their personal treatment or procedure of choice or standard of practice.

In the case of rare diseases, TRICARE recognizes that meeting the usual high standard of evidence may not be possible due to the small numbers of patients available to participate in studies. For rare diseases, a slightly less rigorous level of evidence can be accepted as significant support for use of a treatment on a case-by-case basis. Even for rare diseases, however, 32 CFR 199.4(g)(15)(ii) requires that we determine that a proposed treatment is safe and effective for that disease. The sources that may be consulted to determine if proposed therapy is considered safe and effective are:

1. Trials published in refereed medical literature
2. Formal technology assessments
3. National medical policy organization positions
4. National professional associations
5. National expert opinion organizations