THE ASSISTANT SECRETARY OF DEFENSE



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HEALTH AFFAIRS

MEMORANDUM FOR DIRECTOR, DEFENSE HEALTH AGENCY

SUBJECT: Amended Policy for Assisted Reproductive Services for the Benefit of Seriously or Severely Ill/Injured (Category II or III) Active Duty Service Members

In 2010, the Assistant Secretary of Defense for Health Affairs authorized Assisted Reproductive Technology (ART) for the benefit of severely or seriously ill/injured Active Duty Service members unable to procreate naturally and published Assistant Secretary of Defense for Health Affairs Memorandum, "Policy for Assisted Reproductive Services for the Benefit of Seriously or Severely Ill/Injured (Category II or III) Active Duty Service Members," and implementing guidance, in 2012. The Department remains committed to ensuring the maximum support for our members who have become seriously ill or injured as a result of their service on Active Duty, resulting in injuries or conditions that lead to the inability of those members to procreate without the use of ART. This memorandum continues to authorize benefits for such members to assist in the reduction of the disabling effects of a qualifying condition.

This memorandum amends the 2012 policy to remove the requirement that qualifying individuals be married and to remove the categorical bar on the use of donor (*i.e.*, a non-spouse third-party's) gametes. The amended implementing guidance is attached.

I am directing you to immediately take the necessary steps to implement this amended guidance, including through revisions to the relevant sections of the TRICARE manuals, and any other actions that are necessary and appropriate.

Lester Martinez-López, M.D., M.P.H.

Attachments: As stated

Implementing Guidance for Amended Policy for Assisted Reproductive Services for the Benefit of Seriously or Severely Ill/Injured (Category II or III) Active Duty Service Members

I. CURRENT PROCEDURAL TERMINOLOGY (CPT) PROCEDURE CODES

There are multiple CPT procedures codes associated with assisted reproductive technology (ART) services. The most current codes should be used for those services allowed to be cost-shared.

II. DESCRIPTION

ART services, including sperm retrieval, oocyte retrieval, in-vitro fertilization (IVF), intrauterine insemination (IUI), and blastocyst implantation, are available for seriously or severely ill or injured Service members (Category II and III). The use of the Supplemental Health Care Program is authorized because this is a benefit offered based on the condition of, and exclusively for the benefit of, the severely ill or injured Service member who is unable to procreate without the use of ART (referred to in this memorandum as "qualifying Service members"), and not based on the condition of her or his spouse, TRICARE-enrolled unmarried partner, or TRICARE-enrolled third-party gestational carrier (collectively referred to as "TRICARE-enrolled designee" in this memorandum). Active-duty Service members who desire to participate in the assisted reproductive services program must verify their eligibility for this extended benefit in accordance with section IV below.

III. POLICY GUIDELINES

A. The policy applies to all qualifying Service members, regardless of gender or marital status, who have sustained a serious or severe illness/injury while on active duty that led to the loss of their ability to procreate without the use of ART. This includes, but is not limited to, those suffering neurological, physiological, or anatomical injuries. There is no requirement for the qualifying Service member to demonstrate that they have tried, or intend to try, to procreate with a member of the opposite sex to establish that there has been a loss of their ability to procreate without the use of ART. Rather, this is a medical determination based upon the qualifying Service member's serious or severe illness or injury. TRICARE-enrolled designees, defined in paragraph D below, may also receive ART services under this policy so long as those services are for the benefit of the qualifying Service member. This policy does not authorize provision of any additional care to spouses, partners, or gestational carriers, or any other individuals with conditions impacting their own fertility that is not otherwise covered under the TRICARE Basic program of medical benefits.

B. The policy provides for the provision of ART to assist in the reduction of the disabling effects of the qualifying Service member's condition. The authority for this policy for care outside of the basic medical benefit is derived from Section 1633 of the National Defense Authorization Act for fiscal year 2008. Section 1633 allows the qualifying Service member to

receive services similar to the Extended Care Health Option (ECHO) benefits available to active duty Service member dependents, outside of the standard TRICARE Basic program medical benefit. This "ECHO-like" benefit is provided through the authorization of the expenditure of Supplemental Health Care Program funds and delivery of the needed services in either military medical treatment facilities (MTFs) that offer ART or through authorized private sector care. Although private sector care is available for this benefit, the use of MTFs that offer services covered under the policy should be encouraged, with qualifying Service members given priority for care if there is a waiting list. If the member receives care or medications in the private sector, participating network providers must be used, if available. Preauthorization for every IUI, gamete retrieval, embryo transfer, and IVF cycle is required.

- C. Use of donated third-party gametes or embryos is permitted when provided at the qualifying Service member's expense. Donors are defined by the American Society of Reproductive Medicine (ASRM)¹ and U.S. Food and Drug Administration (FDA) as individuals who provide oocytes, sperm, or embryo and who are not sexually intimate partners of the recipients. Gestational carriers or surrogates are not genetically related to the child and are therefore not considered donors under this definition. All donor gametes and embryos will meet applicable FDA screening and testing requirements. The qualifying Service member is responsible for the arrangements and cost of donor gamete and embryo acquisition (e.g., procedures or associated fees for extraction, screening and testing, storage, or transportation of donor gametes or embryos) regardless of the use of non-identified or directed donation.
- D. Services may be rendered to a qualifying Service member's lawful spouse, unmarried partner, or a third-party gestational carrier, for the benefit of the qualifying Service member in the furtherance of conferring the extended benefits under this policy, only if such spouse, unmarried partner, or third-party gestational carrier is both TRICARE-eligible and enrolled in TRICARE.
- E. Consent to participate in this benefit must be given by the active duty qualifying Service member, as well as their TRICARE-enrolled designee, if applicable.
- F. DoD will cost-share the costs of gamete and/or embryo cryopreservation and storage, but not donor gamete and embryo acquisition (as outlined in paragraph C above), until the member separates or retires, at which point the qualifying Service member is free to continue gamete or embryo storage at their own expense, if desired.
- G. Issues regarding ownership, future use, donation, or destruction of embryos will be governed by the applicable state law and will be the responsibility of the qualifying Service member and their TRICARE-enrolled designee, as applicable, and the facility storing the cryopreserved embryos. DoD's role is limited to paying for this benefit when requested by the consenting qualifying Service member. DoD will not have ownership or custody of cryopreserved gametes or embryos and will not be involved in the ultimate disposition or destruction of excess gametes or embryos. Ultimate disposition or destruction of excess cryopreserved gametes or embryos is not separately reimbursed.

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 $^{^1\} https://www.asrm.org/practice-guidance/practice-committee-documents/recommendations-for-practices-using-gestational-carriers-a-committee-opinion-2022/$

IV. PROCEDURES

- A. The number of cycles of IUI to achieve a pregnancy is limited under this policy to that which the specific clinic deems appropriate but may not exceed six cycles. While IUI is permitted, it is not required as a prerequisite to the receipt of IVF services. The decision on the use of IUI versus IVF will be left to the determination of the treating provider in discussion with the qualifying Service member and TRICARE-enrolled designee, as applicable, as to the most appropriate treatment.
- B. Eligible individuals (e.g., qualifying Service members or their TRICARE-enrolled designee) with an appropriate likelihood of success of achieving pregnancy through IVF, based on the specific clinic's guidelines, will be provided IVF cycles under this benefit, consistent with this memorandum. Infertility testing and treatment, including correction of the physical cause of infertility, are covered in accordance with the TRICARE Policy Manual Chapter 4 Section 17. 1. If a TRICARE-enrolled gestational carrier is utilized, screening is required in accordance with the U.S. Centers for Disease Control and Prevention (CDC), FDA, and American Association of Tissue Banks.
- C. Up to six initiated oocyte retrieval attempts (ovarian stimulation with gonadotropins, and any associated services in preparation of oocyte retrieval) will be provided to the qualifying Service member or their TRICARE-enrolled designee, when provided specifically for the benefit of the qualifying Service member. Regardless of whether oocytes are cryopreserved or immediately fertilized to create embryos for either cryopreservation or fresh embryo transfer, up to three completed oocyte retrievals will be provided to retrieve a reasonable number of oocytes for use for embryo creation. Alternatively, when donor oocytes are utilized, fertilization of a reasonable number of oocytes, as determined necessary to achieve the intent of this policy for the benefit of the qualifying Service member, is covered.
- D. For the purposes of this policy, a completed IVF cycle is defined as a fresh or frozen embryo transfer, regardless of the number of embryos transferred or source of the embryos. Up to three completed IVF cycles will be provided to the qualifying Service member or their TRICARE-enrolled designee, when provided specifically for the benefit of the qualifying Service member.
- E. The restrictions, as outlined in paragraph C and D, are calculated on the basis of the total lifetime retrievals and cycles used by the qualifying Service member, not by the TRICARE-enrolled designee.
- F. Assisted reproductive service centers with capability to provide full services, including alternative methods of sperm aspiration, will be invited to participate in the TRICARE network by the managed care support contractors and designated providers. (Membership in the American Society for Reproductive Medicine, with associated certification(s), is highly recommended for network providers. Reporting outcomes consistent with Fertility Clinic Success Rate and Certification Act of 1992 (Public Law 102-493) is mandatory.) When a network provider is not available, the ECHO-like benefits provided under this policy may be

provided by any TRICARE-authorized provider, including those authorized pursuant to 32 C.F.R. Part 199.6(e).

- G. IVF cycles will be accomplished in accordance with the standard accepted practices as determined by the provider clinic using gonadotropins which may include concentrated mixtures of follicle stimulating hormone or follicle stimulating hormone and luteinizing hormone given as injection. These medications should be obtained through the TRICARE Mail Order Pharmacy, a TRICARE Network Pharmacy, or MTF, if available and doing so provides a cost-savings to the Government.
- H. Anesthesia or conscious sedation will be provided for the oocyte retrieval and sperm aspiration in accordance with applicable TRICARE Policy Manual provisions. For qualifying Service members, sperm aspiration through microsurgical epididymal sperm aspiration, percutaneous epididymal sperm aspiration or non-surgical fine needle aspiration may be accomplished in conjunction with egg retrieval. Vibratory stimulation or electro-ejaculation may be used, if appropriate, for the qualifying Service member.
- I. Intracytoplasmic sperm injection will be covered when determined by the IVF clinic to be beneficial for fertilization.
- J. Embryo transfer, in accordance with guidelines provided by the American Society for Reproductive Medicine, will be accomplished in accordance with accepted clinic practices.
- K. Healthy embryos that progress to an appropriate stage, as assessed by the embryologist, in excess of those used for a fresh embryo transfer, may be cryopreserved. Storage of cryopreserved embryos will be a covered benefit in accordance with this memorandum so long as the qualifying Service member remains eligible for this benefit. Ownership of cryopreserved embryos will be the responsibility of the qualifying Service member and their TRICARE-enrolled designee, as applicable, and documented in accordance with clinic policies.
- L. Both fresh and frozen embryo transfers are included in this benefit, based on the provider and patient discussion to achieve optimal embryo implantation.

V. PROCESS FOR PARTICIPATING IN ASSISTED REPRODUCTIVE SERVICES PROGRAM

- A. For an active duty Service member to be eligible under this policy, there must be documentation of Category II or III illness or injury designation as defined in Department of Defense Instruction 1300.24, "Recovery Coordination Program," December 1, 2009.
- B. A referral is required from the qualifying Service member's Primary Care Manager or other provider significantly involved in the care of the qualifying condition(s) or the impact of those condition(s) on the qualifying Service member's fertility.
- C. The information provided to the Managed Care Support Contractor (MCSC) with the referral must include the following:

- 1. Service member's qualifying diagnosis(es);
- 2. Confirmation of Category II or III status;
- 3. Summary of relevant medical information supporting category designation;
- 4. Identification of any TRICARE-enrolled designee and the ART services to be provided to the designee for the benefit of the qualifying Service member;
- 5. Name of provider of reproductive services requested to be used, if known; and
- 6. Confirm completion and uploading of Defense Health Agency (DHA) Form 407, Assisted Reproductive Services for the Benefit of Seriously or Severely Ill/Injured (Category II or III) Active Duty Service Members Qualifying Service Member Information and Attestation, which may be found at the <u>DHA Forms Library</u>, attesting that the ART services provided under this policy are exclusively for the purpose and intent of enabling the qualifying Service member to become a parent and that the qualifying Service member intends to assume a parental relationship with any child born as a result of the ART services covered under this policy.
- D. The referral must be sent electronically to the TRICARE Managed Care Service Contractor where verification of the qualifying Service member's eligibility for this ECHO-like benefit will be completed.
- E. If applicable, a referral must also be submitted for the TRICARE-enrolled designee receiving ART services for the benefit of the qualifying Service member. The information provided to the MCSC with the referral must include the following:
 - 1. Qualifying Service member's name and DoD ID number;
 - 2. Confirmation of qualifying Service member's Category II or III status; and
 - 3. Summary of relevant medical information of the qualifying Service member's supporting category designation
- F. The Managed Care Support Contractors will process the referral for authorization and process claims in accordance with the TRICARE Operations Manual, Chapter 17, Section 3. This authorization will allow the use of the SHCP funds for this service.
- G. In order to verify eligibility, number of attempts and completed attempts, and all other requirements, all IUI, gamete retrieval, embryo transfers, and IVF cycles must be preauthorized.

VI. EXCLUSIONS

- A. No portion of this benefit will be used to pay for services or associated fees for the extraction, screening and testing, storage, or transportation of donor gamete or donor embryo acquisition for use under this benefit.
- B. Compensation of any kind, from any source, including from the Department of Defense or the qualifying Service member, to a partner or third-party gestational carrier for involvement in supporting the effort to overcome the qualifying Service member's loss of the ability to procreate without the use of ART is prohibited. A qualifying Service member may request an exception to this prohibition to personally reimburse their TRICARE-enrolled designee for reasonable travel costs, or any reasonable co-pays and cost shares, associated with medical care provided to the TRICARE-enrolled designee as a result of this policy. Such requests will be made in writing to the Assistant Secretary of Defense for Health Affairs.
- C. Care that is not for the benefit of the qualifying Service member will not be cost-shared, including situations where the qualifying Service member does not intend to, and has not signed a written attestation affirming an intent to, be a parent to the resulting child.
- D. This benefit is not available if the qualifying Service member is deceased or their serious or severe illness or injury prevents them from providing consent.
- E. Care provided to individuals who are not TRICARE-eligible and enrolled cannot be authorized and will not be cost-shared.
- F. Cryopreservation of gametes or embryos in anticipation of deployment is not covered under this policy and will not be cost-shared.