OFFICE OF THE UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

PERSONNEL AND
READINESS

The Honorable John McCain
Chairman
Committee on Armed Services
United States Senate
Washington, DC 20510

OCT 17 2016

Dear Mr. Chairman:

The enclosed report is in response to Senate Report 114-255, page 202, accompanying S. 2943, the National Defense Authorization Act for Fiscal Year 2017, which requests the Department provide a report on the implementation of authority for provisional TRICARE coverage for emerging health care services and supplies. Key elements include: the actions undertaken, the services and supplies for which the Department has granted provisional TRICARE coverage, and impacts provisional TRICARE coverage authority has had on access to and provider reimbursement for services and supplies.

As a result of the Provisional Coverage Program, surgical treatment for Femoroacetabular Impingement Syndrome was approved and coverage began on January 1, 2016. Transcranial magnetic stimulation for the treatment of major depressive disorder and two-level cervical disc replacement were also identified for provisional coverage review, but ultimately covered under the TRICARE Basic Program based on the existence of sufficient reliable evidence. The procedures established to review emerging health care services and supplies will continue to be a valuable tool for informing not only TRICARE private sector care coverage decisions, but also the direct care system, regarding the safety, efficacy, and appropriate clinical indications for emerging treatments and technologies, resulting in greater consistency in availability and utilization of these emerging treatments and technologies between private sector care and the direct care system. We will continue to review other treatments for possible provisional coverage.

Thank you for your interest in the health and well-being of our Service members, veterans, and their families. A similar letter is being sent to the House Armed Services Committee.

Sincerely,

Peter Levine
Performing the Duties of the Under Secretary of
Defense for Personnel and Readiness

Enclosure:
As stated

cc:
The Honorable Jack Reed
Ranking Member

OFFICE OF THE UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

PERSONNEL AND
READINESS

The Honorable William M. "Mac" Thornberry
Chairman
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

OCT 17 2016

Dear Mr. Chairman:

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Sincerely,

Peter Levine
Performing the Duties of the Under Secretary of
Defense for Personnel and Readiness

Enclosure:
As stated

cc:
The Honorable Adam Smith
Ranking Member

Report to Armed Services Committees

The Department of Defense

Report on Implementation of Authority for Provisional TRICARE Coverage for Emerging Health Care Services and Supplies

The estimated cost of this report or study for the Department of Defense is approximately $$7,700 for the 2016 Fiscal Year. This includes $0 in expenses and $7,700 in DoD labor.

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EXECUTIVE SUMMARY

The Department of Defense (DoD) presents this report in response to Senate Report 114-255, page 202, accompanying S. 2943, the National Defense Authorization Act for Fiscal Year 2017 which requests the Secretary of Defense to submit a report on the implementation of the Department's authority for provisional TRICARE coverage for emerging health care services and supplies pursuant to section 1079c of title 10, United States Code.

In accordance with the required elements, this report describes the following:

1. The actions undertaken to implement the authority to provide provisional TRICARE coverage for emerging health care services and supplies;
2. The services and supplies for which the Department has granted provisional TRICARE coverage;
3. The rationale, for implementation of demonstration projects for TRICARE coverage of such services and supplies in lieu of granting provisional TRICARE coverage; and
4. The impact that implementation of provisional TRICARE coverage authority has had on access to and provider reimbursement for services and supplies, such as molecular pathology laboratory developed tests, as compared to non-coverage of those services and supplies.

The Defense Health Agency (DHA) developed a Concept of Operations (CONOPS) for use in evaluating emerging health technologies and services for provisional coverage. The process includes consultation with multiple stakeholders within the DHA, to include representatives from the TRICARE Health Plan Division, Clinical Support Division, Office of General Counsel and Research Development and Acquisition (RDA) Directorate. Also, members of the Medical Directors Working Group (MDWG) which includes Service representatives and Communities of Interest (CoIs) consisting of Service clinical subject matter experts provide critical input during the evaluation process. The CoIs assess the current standard of practice, review clinical evidence, and evaluate the current state of clinical research for emerging health care services.

Five emerging health care services have been evaluated to date. Surgical treatment for Femoroacetabular Impingement (FAI) syndrome was the first treatment approved for provisional coverage. Transcranial Magnetic Stimulation (TMS) for Treatment of Major Depressive Disorder and Two-Level Cervical Disc Replacement after review by the CoI were found to have sufficient reliable evidence to support approval and coverage under the TRICARE Basic program. Single and Multi-Level Lumbar Disc Replacement were reviewed, but not recommended for provisional coverage by the Service clinical subject matter experts at this time.

No new demonstration projects for TRICARE coverage of services and supplies have been implemented in lieu of granting provisional TRICARE coverage since enactment of this legislative authority.

Provisional coverage of FAI surgery began on January 1, 2016. During the first six months of implementation, 1,497 surgical procedures were performed at a cost of $3,338,338.00.

INTRODUCTION

This report responds to Senate Report 114-255, page 202, accompanying S. 2943, the National Defense Authorization Act for Fiscal Year 2017 request for the Secretary of Defense to submit a report on the implementation of the Department's authority for provisional TRICARE coverage for emerging health care services and supplies pursuant to section 1079c of title 10, United States Code. The statute allows TRICARE to cover health care services under a "provisional" category for services and supplies widely recognized in the United States as being sufficiently safe and effective, but which fail to meet the "hierarchy of reliable evidence" (as defined in 32 CFR 199.2) required for coverage under the TRICARE basic program. This authority allows provisional coverage for a defined service or technology for a total of five years. Prior to the expiration of provisional coverage, the Department will make a determination on coverage under the TRICARE Basic Program, if any, that will follow provisional coverage.

This report includes:

(1) Actions undertaken to implement the authority to provide provisional TRICARE coverage for emerging health care services and supplies;

(2) Services and supplies for which the Department has granted provisional TRICARE coverage;

(3) Rationale for implementation of demonstration projects for TRICARE coverage of such services and supplies in lieu of granting provisional TRICARE coverage; and

(4) Impact that implementation of provisional TRICARE coverage authority has had on access to and provider reimbursement for services and supplies, such as molecular pathology laboratory developed tests, as compared to non-coverage of those services and supplies.

DOD DISCUSSION OF SPECIFIC ISSUES:

1. Actions undertaken to implement the authority to provide provisional TRICARE coverage for emerging health care services and supplies

DHA stood up an Integrated Project Team (IPT) tasked with developing a plan to execute the authority to provide provisional coverage for emerging health care services and supplies. This workgroup created an internal CONOPS for use in evaluating emerging health technologies and services proposed for provisional coverage. The CONOPS provides a systematic approach and repeatable process for the review of emerging technologies and treatments for provisional coverage consideration. The process includes consultation with multiple stakeholders, including representatives from the TRICARE Health Plan Division, Clinical Support Division, Office of General Counsel, RDA Directorate, MDWG with Service representation and CoIs consisting of Service clinical subject matter experts. The CONOPS was approved by the Director, DHA.

Following CONOPS approval, the IPT developed the structure to implement the CONOPS. Since the existing MDWG already had responsibility for identifying proven advancements in practice, new trends and emerging technologies, the MDWG Charter was expanded to include responsibility to identify, evaluate, prioritize and recommend emerging health care products and services for review under the Provisional Coverage Program. The MDWG voting members consist of the Service Medical Directors (Army, Navy, and Air Force) and Senior Medical Director, Office of the Director of the TRICARE Regional Offices. A prioritization matrix was created to assist the voting members. The matrix criteria include Readiness/Strategic Value, Interest Level, and Expected Utilization. After review and prioritization, the MDWG presents their recommendations to the Director, Healthcare Operations (HCO) for approval. Approved topics have a CoI created to assess the clinical evidence. The CoIs evaluate the standard of practice and review relevant clinical evidence. In addition, since provisional coverage can only be in effect for five years, each item is evaluated to determine the current state of research. In general, those new treatments/ technologies with a low likelihood of meeting the reliable evidence standard in five years may not be good candidates for provisional coverage. Since emerging technologies and treatments are continuously evolving, the MDWG will continue to monitor, review, and prioritize or reprioritize health care services for review and bring their recommendations to the Director, HCO.

2. Services and supplies for which the Department has granted provisional TRICARE coverage

Surgical treatment for FAI syndrome was the first emerging treatment to be evaluated and approved for provisional coverage effective January 1, 2016. This provisional coverage will terminate in five years on December 31, 2020. There are three well controlled clinical trials in progress comparing FAI surgery to non-surgical treatment. It is expected these studies will be published during the five year provisional coverage time limit. If the published results of the three clinical trials demonstrate that FAI surgery is a safe and effective treatment, then the usual process of preparing a Medical Benefit Determination (MBD) will be accomplished for permanent TRICARE coverage. If at any time during the five year provisional coverage term, clinical research findings indicate it is found to be unsafe or ineffective, then a recommendation will be made to terminate provisional coverage.

In addition to Surgical Treatment for FAI syndrome, four other emerging technologies/ treatments were evaluated. All five evaluations are summarized in the table below:

Technology/Treatment Evaluated for Provisional Coverage	Outcome of Evaluation
Surgical Treatment for FAI Syndrome	Sufficient evidence existed to support the determination that open, arthroscopic, and combined surgeries of the hip for the treatment of FAI syndrome are widely recognized in the U.S. as being safe and effective. Provisional coverage was approved by the Assistant Secretary of Defense for Health Affairs and became effective January 1, 2016.
TMS for Treatment of Major Depressive Disorder	Sufficient evidence existed to support the determination that TMS for treatment of Major Depressive Disorder met the hierarchy of reliable evidence to be covered under the TRICARE Basic program. The MBD was approved by the Director, DHA and the change to policy was published in the TRICARE Policy Manual on May 10, 2016.
Multi-Level Lumbar Disc Replacement	Evaluation by the CoI determined sufficient evidence and ongoing research did not exist to support a recommendation for provisional coverage. This evaluation was completed in February, 2016.
Single-Level Lumbar Disc Replacement	Evaluation by the CoI determined sufficient evidence and ongoing research did not exist to support a recommendation for provisional coverage. This evaluation was completed in February, 2016.
Two-Level Cervical Disc Replacement	Sufficient evidence existed to support the determination that two-level cervical disc replacement for the treatment of degenerative disc disease, intractable radiculopathy and or myelopathy met the requirements set forth in the hierarchy of reliable evidence to be covered under the TRICARE Basic program. The MBD was approved by the Director, DHA and the change to policy will be published in the TRICARE Policy Manual.

Two of the above health care services were ultimately found to meet the existing TRICARE hierarchy of reliable evidence for coverage under the TRICARE Basic program, and a MBD was completed for these procedures instead. A MBD is the standard process the DHA uses to review a health care service under the reliable evidence hierarchy. If the reliable evidence standard is met, the health care service is covered under the TRICARE Basic Program and the five year provisional coverage limitation does not apply.

Information regarding the Provisional Coverage Program was posted on the TRICARE website at http://www.tricare.mil/provisionalcoverage under “Special Programs” and a tool kit with beneficiary education materials was distributed to relevant stakeholders by the DHA Strategic Communication Division on December 4, 2015.

3. ***The rationale for implementation of demonstration projects for TRICARE coverage of such services and supplies in lieu of granting provisional TRICARE coverage***

   At this time, no new demonstration projects for TRICARE coverage of services and supplies have been implemented in lieu of granting provisional TRICARE coverage following the enactment of section 1079c of title10, United States Code.

   With respect to molecular pathology laboratory developed tests (LDTs), the Department used its demonstration authority to address TRICARE coverage of LDTs that have not yet been reviewed by the Food and Drug Administration. The LDT demonstration project, as published in the Federal Register notice and implemented through provisions in the TRICARE Operations Manual, commenced in the summer of 2014, and governs TRICARE coverage of LDTs. These existing processes are working as intended and there is no need to use the provisional coverage authority.

4. ***The impact that implementation of provisional TRICARE coverage authority has had on access to and provider reimbursement for services and supplies, such as molecular pathology laboratory developed tests, as compared to non-coverage of those services and supplies***

   The impact of implementation of provisional coverage on access is demonstrated where FAI surgery was performed on 1,497 TRICARE beneficiaries in the first six months of coverage. For these FAI surgeries, institutions and individual providers where reimbursed a total of $3,388.388.00 for services and supplies. Without provisional coverage these beneficiaries would not have had access to this surgery and would either had to self-pay or not have surgery at all.

CONCLUSION:

Provisional coverage authority has given the Department the ability to cover emerging health care services that would otherwise not be covered by TRICARE in the civilian network. The data show provisional coverage of FAI surgery has been utilized by a significant number of beneficiaries during the first six months of coverage.

Interestingly, several other health care services, which were being performed in the direct care system and thought to be widely recognized as safe and effective and thus identified for review for Provision Coverage, were ultimately found to meet the existing TRICARE hierarchy of reliable evidence for coverage under the TRICARE Basic program. As a result, MBDs have been completed and TRICARE coverage extended for transcranial magnetic stimulation for treatment of major depressive disorder and two-level cervical disc replacement for the treatment of degenerative disc disease, intractable radiculopathy and/or myelopathy.

DHA will periodically review and prioritize emerging health care services for a CoI assessment. The goal is to have multiple CoIs established at any one time and as one CoI completes its work, a new CoI can be formed. This is a dynamic and flexible process that includes invaluable input

from the Services and Service clinical experts, since many Military Treatment Facilities, especially our academic medical centers, are at the forefront of evaluating and providing emerging health care services. These established procedures will continue to be a valuable tool for informing TRICARE coverage decisions regarding the safety, efficacy and appropriate clinical indications for emerging treatments and technologies, resulting in greater availability and utilization of these emerging treatments and technologies that are widely recognized in the United States as being safe and effective.

Appendix: Excerpt from S. Rept. 114-255, page 202

Implementation of authority for provisional TRICARE coverage for emerging health care services and supplies

The committee directs the Secretary of Defense to submit a report, by September 30, 2016, to the Committees on Armed Services of the Senate and the House of Representatives on implementation of the Department's authority for provisional TRICARE coverage for emerging health care services and supplies pursuant to section 1079(c) of title 10, United States Code. The report shall describe the following: (1) the actions undertaken to implement the authority to provide provisional TRICARE coverage for emerging health care services and supplies; (2) the services and supplies for which the Department has granted provisional TRICARE coverage; (3) the rationale, if any, for implementation of demonstration projects for TRICARE coverage of such services and supplies in lieu of granting provisional TRICARE coverage; and (4) the impact that implementation of provisional TRICARE coverage authority has had on access to and provider reimbursement for services and supplies, such as molecular pathology laboratory developed tests, as compared to non-coverage of those services and supplies.