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TRICARE
MANAGEMENT ACTIVITY

MB&RB

CHANGE 54
6010.57-M
SEPTEMBER 8, 2011

PUBLICATIONS SYSTEM CHANGE TRANSMITTAL FOR TRICARE POLICY MANUAL (TPM), FEBRUARY 2008

The TRICARE Management Activity has authorized the following addition(s)/revision(s).

CHANGE TITLE: **HOME INFUSION THERAPY**

CONREQ: 15283

PAGE CHANGE(S): See page 2.

SUMMARY OF CHANGE(S): This change creates a preauthorization requirement for home infusion therapy, and requires non-homebound beneficiaries to obtain home infusion drugs from the TRICARE Pharmacy (TPharm) program.

EFFECTIVE DATE: September 30, 2011.

IMPLEMENTATION DATE: Upon direction of the Contracting Officer.

This change is made in conjunction with Feb 2008 TRM, Change No. 52.

Ann N. Fazzini
Chief, Medical Benefits and Reimbursement Branch

ATTACHMENT(S): **16 PAGE(S)**
DISTRIBUTION: **6010.57-M**

WHEN PRESCRIBED ACTION HAS BEEN TAKEN, FILE THIS TRANSMITTAL WITH BASIC DOCUMENT.

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Section 7.1, pages 1 and 2	Section 7.1, pages 1 and 2
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Chapter 1 Section 7.1

Special Authorization Requirements

Issue Date: August 4, 1988
Authority: 32 CFR 199.4(a)(12), 32 CFR 199.5(h)(3) and 32 CFR 199.15(b)(4)

1.0 POLICY

Unless otherwise specifically excepted, the adjudication of the following types of care is subject to the following authorization requirements:

1.1 Adjunctive dental care must be preauthorized.

1.2 Dental anesthesia and institutional benefit must be preauthorized. See Chapter 8, Section 13.2, paragraph 2.5.

1.3 Extended Care Health Option (ECHO) benefits must be authorized in accordance with Chapter 9, Section 4.1.

1.4 Effective October 1, 1991, preadmission and continued stay authorization is required before nonemergency inpatient mental health services may be cost-shared (includes Residential Treatment Center (RTC) care and alcoholism detoxification and rehabilitation). Effective September 29, 1993, preadmission and continued stay authorization is also required for all care in a Partial Hospitalization Program (PHP).

1.5 Effective November 18, 1991, psychoanalysis must be preauthorized.

1.6 The Director, TRICARE Management Activity (TMA), or designee, may require preauthorization of admission to inpatient facilities.

1.7 Organ and stem cell transplants are required to be preauthorized. For organ and stem cell transplants, the preauthorization shall remain in effect as long as the beneficiary continues to meet the specific transplant criteria set forth in this TRICARE Policy Manual (TPM), or until the approved transplant occurs.

1.8 Infusion therapy delivered in the home must be preauthorized in accordance with Chapter 8, Section 20.1.

1.9 Effective for dates of service **June 1, 2010**, Skilled Nursing Facility (SNF) care received in the U.S. and U.S. territories must be preauthorized for TRICARE dual eligible beneficiaries. The TRICARE Dual Eligible Fiscal Intermediary Contract (TDEFIC) contractor will preauthorize SNF care beginning on day 101, when TRICARE becomes primary payer. For those beneficiaries inpatient on the effective date, a preauthorization will be required August 1, 2010. See the TRICARE Operations

Manual (TOM), Chapter 7, Section 2 and the TRICARE Reimbursement Manual (TRM), Chapter 8, Section 2.

1.10 Each TRICARE Regional Managed Care Support Contractor (MCSC) may require additional care authorizations not identified in this section. Such authorization requirements may differ between regions. Beneficiaries and providers are responsible for contacting their contractor for a listing of additional regional authorization requirements.

Note: When a beneficiary has "other insurance" that provides primary coverage, preauthorization requirements in paragraph 1.10. will not apply. Any medically necessary reviews the MCS contractor believes are necessary, to act as a secondary payor, shall be performed on a retrospective basis. The conditions for applying this exception are the same as applied to the Non-Availability Statement (NAS) exception in Section 6.1, paragraph 3.1.

1.11 Provider payments are reduced for the failure to comply with the preauthorization requirements for certain types of care. See the TRM, Chapter 1, Section 28.

2.0 EXCEPTIONS

2.1 For dual eligible beneficiaries, these requirements apply when TRICARE is primary payer. As secondary payer, TRICARE will rely on and not replicate Medicare's determination of medical necessity and appropriateness in all circumstances where Medicare is primary payer. In the event that TRICARE is primary payer for these services and preauthorization was not obtained, the contractor will obtain the necessary information and perform a retrospective review.

2.2 The requirement that a TRICARE Prime enrollee obtain a referral/authorization from their Primary Care Manager (PCM) to receive the H1N1 immunization from a non-network, TRICARE-authorized provider has been temporarily waived from October 1, 2009 to May 1, 2010. During this period, Prime enrollees may obtain the H1N1 immunization from a non-network TRICARE-authorized provider without prior authorization or PCM referral. Point Of Service (POS) cost-shares normally associated with non-referred care obtained by Prime enrollees from non-network providers without appropriate authorization will not apply during this period.

- END -

Chapter 8

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2.5	Home Prothrombin Time (PT) International Normalized Ratio (INR) Monitor
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19.1	Smoking Cessation Counseling
20.1	Infusion Drug Therapy Delivered In The Home

Chapter 8 Section 9.1

Pharmacy Benefits Program

Issue Date: August 2002
Authority: 32 CFR 199.2(b), 32 CFR 199.4(b)(2)(vi), (b)(3)(iii), (b)(5)(v), (d)(3)(vi), (e)(11)(i), 32 CFR 199.5(d)(12); 32 CFR 199.17, and 10 USC 1074g

1.0 DESCRIPTION

1.1 General

The TRICARE Pharmacy (TPharm) benefit includes retail and mail order prescription services, medications provided by physicians and other appropriate clinicians, and pharmaceutical agents provided in support of home health care. TRICARE uses a number of contractors to administer the benefit.

1.2 Retail Prescription Service

Retail pharmacy services, network and non-network, will be provided under a TPharm contract and will be subject to the Uniform Formulary. The TRICARE formulary is found at http://www.tricareformularysearch.org. The retail pharmacy contractor is responsible for administering claims related to pharmaceuticals dispensed by an authorized provider with a National Council of Prescription Drug Programs (NCPDP) or other nationally recognized pharmacy designation.

1.3 Mail Order Prescription Service

Mail order prescription services are provided under a TPharm contract and will be subject to the Uniform Formulary. The TRICARE formulary is found at http://www.tricareformularysearch.org.

1.4 Medical Claims That Include Pharmaceutical Agents

Pharmaceutical agents provided by physicians and other appropriate clinicians, and pharmaceutical agents provided in support of home health care are processed by the Managed Care Support Contractor(s) (MCSC). Claims for pharmaceutical agents (e.g., injectables) not appropriate for self-administration are the responsibility of the MCSC.

1.5 Infusion Drug Therapy Delivered In The Home

When injectable and infusion drug therapy are medically necessary, and delivery and administration in the home is appropriate the MCSC shall provide prior authorization of injectable or infused drugs to a TRICARE authorized pharmacy in order for the pharmaceutical agent to be fulfilled under the pharmacy benefit pursuant to Section 20.1, "Infusion Drug Therapy Delivered in

the Home".

1.6 Overseas Claims

The TRICARE overseas claims processor (see the TRICARE Operations Manual (TOM), Chapter 24, Section 9) processes pharmaceutical claims from most overseas locations. As of June 1, 2004, the TPharm contractor processes network and non-network retail pharmaceutical claims in Puerto Rico, the U.S. Virgin Islands, Northern Mariana Islands, and Guam.

2.0 POLICY

2.1 Formulary

Formulary management will be the responsibility of the Government as defined by 32 CFR 199.21, Pharmacy Benefits Program. This regulation establishes procedures for the inclusion of pharmaceutical agents on a Uniform Formulary based upon relative clinical effectiveness and cost effectiveness; establishes cost-sharing requirements, including a tiered copayment structure, for generic, formulary and non-formulary pharmaceutical agents; establishes procedures to assure the availability of pharmaceutical agents not included on the Uniform Formulary to eligible beneficiaries at the non-formulary cost-share tier; establishes procedures to provide, when clinically necessary, pharmaceutical agents not included on the Uniform Formulary under the same terms and conditions as an agent on the Uniform Formulary; establishes procedures to assure the availability of clinically appropriate non-formulary pharmaceutical agents to members of the uniformed services; establishes procedures for prior authorization when required; and establishes a Department of Defense Pharmacy and Therapeutics Committee (DoD P&T Committee) and a Uniform Formulary Beneficiary Advisory Panel. All formulary decisions, to include prior authorization requirements, designation of non-formulary agents, quantity limits, and other medication use policies will be communicated to all contractors who have responsibility for administering the pharmacy benefit.

2.2 General Prescription Coverage

2.2.1 The Pharmacy Benefits Program generally requires mandatory substitution of generic drugs in accordance with 32 CFR 199.21(j)(2). If state law prohibits generic substitution on drugs, the contractor, at the direction of the government, shall be able to process the brand product.

2.2.2 Eligible beneficiaries shall pay a copayment for drug claims that are cost-shared under the Pharmacy Benefit Program in accordance with the TRICARE Reimbursement Manual (TRM), Chapter 2, Addendum B.

2.2.3 TRICARE is the secondary payor on claims where Other Health Insurance (OHI) coverage exists. OHI claims are reimbursed in accordance with TRM, Chapter 4, Section 3. Reimbursement will be the lesser of the TRICARE allowed amount or the remaining amount after OHI payment.

2.2.4 Labeled Indications. Pharmaceutical agents may be cost-shared when:

- The pharmaceutical agent is approved for marketing by the U.S. Food and Drug Administration (FDA);

- The pharmaceutical agent is prescribed by a provider, acting within the scope of his/her license, for its labeled indication; and

- The pharmaceutical agent is furnished by a provider in accordance with all applicable state laws and licensing requirements.

2.2.5 Coverage may also be considered for unlabeled or off-label uses of drugs that are FDA approved drugs that are used for indications or treatments not included in the approved labeling. Approval for reimbursement of unlabeled or off-label uses requires review for medical necessity, and also requires demonstrations from medical literature, national organizations, or technology assessment bodies that the unlabeled or off-label use of the drug is safe, effective, and in accordance with nationally accepted standards of practice in the medical community. As presented in order of relative weight in 32 CFR 199.2, reliable evidence means:

- Well controlled studies of clinical meaningful endpoints, published in refereed medical literature.

- Published formal technology assessments.

- Published reports of national professional medical associations.

- Published national medical policy organizations.

- Published reports of national expert opinion organizations.

2.2.6 Pharmaceutical agents grandfathered by the Federal Food, Drug and Cosmetic Act of 1938 may be cost-shared as if FDA approved.

2.2.7 Insulin and related supplies may be cost-shared for known diabetic patients, even though a prescription may not be required for purchase.

2.2.8 Pharmaceutical agents with FDA "orphan drug" designation and marketing approval may be cost-shared when used in the treatment of a rare disease or condition. For the purpose of the Pharmacy Benefits Program, TRICARE adopts the FDA definition of the term "rare disease or condition."

2.2.9 Legend vitamins may be cost-shared only when used as a specific treatment of a medical condition. In addition, prenatal vitamins that require a prescription in the United States may be cost-shared. Prenatal vitamins requiring a prescription are covered for prenatal care only.

2.2.10 The DoD establishes quantity limits and prior authorizations for certain pharmaceutical agents. Prior authorization request forms, criteria, and list of pharmaceutical agents with established quantity limits are available at: http://www.tricare.mil/pharmacy/unif_form.cfm.

3.0 EXCLUSIONS

3.1 Pharmaceutical agents prescribed or furnished by a member of the patient's immediate family or a person living in the beneficiary's or sponsor's household.

3.2 Pharmaceutical agents, including compounded preparations, that are available over the counter.

3.3 Investigational pharmaceutical agents with FDA "Group C" designation have reproducible efficacy in one or more specific tumor types. Such a drug has altered or is likely to alter the pattern of treatment of the disease, and can be safely administered by properly trained physicians without specialized supportive care facilities. TRICARE may not cost-share use of Group C-designated pharmaceutical agents, because authorization for Group C distribution for a specific indication is not equivalent to formal FDA approval for that indication. Medical care related to the use of Group C-designated pharmaceutical agents may be cost-shared only when the care would have been provided in the absence of the use of the Group C-designated drug.

3.4 Orphan pharmaceutical agents without marketing approval, but which are made available on a compassionate-use basis, may not be cost-shared.

3.5 Under the FDA treatment Investigational New Drug (IND) regulations enacted in 1987, pharmaceutical agents that are in controlled clinical trials can be provided outside those trials to treat patients with serious or immediately life-threatening diseases for which no comparable or satisfactory alternate therapy exists. TRICARE may not cost-share treatment INDs because they have not received FDA marketing approval. However, medical care related to the use of treatment INDs may be cost-shared when the patient's medical condition warrants their administration and the care is provided in accordance with generally accepted standards of medical practice.

3.6 Medical foods are not covered under the TPharm benefit. The term "medical food", as defined in section 5(b) of the Orphan Drug Act (21 USC § 360ee(b)(3)) is "a food which is formulated to be consumed or administered enterally under the supervision of a physician, and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation."

3.7 Irinotecan (Camptosar®) for treatment of metastatic esophageal cancer is unproven.

4.0 UTILIZATION MANAGEMENT

4.1 Utilization management is the responsibility of the contractor with responsibility for the venue distributing the pharmaceuticals. Should another contractor require data about pharmaceutical prescribing practices of clinicians or the pharmaceuticals prescribed to a patient, the contractor requiring the information may submit a request for data to the Contracting Officer (CO). The requesting contractor shall commit to paying all costs associated with retrieving and providing any data. No contractor will be required to develop or provide data that are not available in the contractor's data warehouse.

4.2 The contractors shall screen prescription claims for potential over-utilization and substance abuse. If a potential drug abuse situation is identified by the MCSC, the pharmacy contractor, a private physician, a physician-reviewer in the course of business for the contractor, or a physician in a hospital setting, the beneficiary shall be placed on 100% prepayment review. The Government cannot cost share benefits to support or maintain potential drug abuse situations. This is true, whether or not the pharmaceutical agents are obtained by legal means, and are otherwise eligible for benefit consideration under other circumstances. The pharmacy contractor, in conjunction with the managed care support contractor or responsible military treatment facility shall:

4.2.1 Pend all claims for the beneficiary;

4.2.2 Establish the necessity for the pharmaceutical agents and their appropriateness based on diagnosis or definitive symptoms;

4.2.3 Deny all related claims if a drug abuse situation does exist, including office visits or emergency room visits if the purpose of the visit was to obtain pharmaceutical agents; and

4.2.4 Reopen prior claims (most recent 12 months) for the beneficiary and review those claims to determine whether or not drug abuse existed at the time the earlier claims were paid. If drug abuse is ascertained for prior claims, recoupment action shall be taken for the erroneous payments.

4.3 The contractor shall request the beneficiary to select a physician, who will act as the primary care physician coordinating all care and making referrals when appropriate. For Prime enrollees, the contractors shall take action to manage the beneficiary's treatment as appropriate. The contractor shall not submit these cases to the TMA Program Integrity (PI) Office unless potential fraud, such as altered prescriptions or drug receipts, or aberrant prescribing patterns by the physician is identified.

4.4 Additionally, beneficiaries will be required to designate a primary care provider responsible for managing all prescriptions. Beneficiaries will be informed that any prescription written by other than the designated provider shall be denied authorization for dispensing through network retail pharmacies and, additionally, that any TRICARE claim for prescriptions filled by a non-network retail pharmacy will be denied reimbursement. This process will be coordinated between the managed care support contractor, the pharmacy contractor, and the Pharmacy Operations Center (POC).

Note: Beneficiaries are entitled to benefits by law. Beneficiaries cannot be sanctioned to preclude them from seeking benefits for medical care which is appropriate and medically necessary.

5.0 EFFECTIVE DATES

5.1 Labeled uses: the date of FDA approval for the specific indication.

5.2 Off-labeled uses: the date that reliable evidence establishes the safety and efficacy of the drug for that specific use.

5.3 Orphan pharmaceutical agents: the date of FDA marketing approval.

- END -

Chapter 8 Section 20.1

Infusion Drug Therapy Delivered In The Home

Issue Date: September 7, 2011
Authority: 32 CFR 199.2 and 32 CFR 199.6(f)

1.0 CPT[1] PROCEDURE CODES

99601, 99602

2.0 HCPCS CODE

S9430

3.0 BACKGROUND

3.1 32 CFR 199.2 defines appropriate medical care as:

- Services performed in connection with the diagnosis or treatment of disease or injury, pregnancy, mental disorder, or well-baby care which are in keeping with the generally accepted norms for medical practice in the United States;

- The authorized individual professional provider rendering the medical care is qualified to perform such medical services by reason of his or her training and education and is licensed or certified by the state where the service is rendered or appropriate national organization or otherwise meets CHAMPUS standards; and

- The services are furnished economically. For purposes of this part, "economically" means that the services are furnished in the least expensive level of care or medical environment adequate to provide the required medical care regardless of whether or not that level of care is covered by CHAMPUS.

3.2 32 CFR 199.2 defines homebound as:

- A beneficiary's condition is such that there exists a normal inability to leave home and, consequently, leaving home would require considerable and taxing effort. Any absence of an individual from the home attributable to the need to receive health care treatment--including regular absences for the purpose of participating in therapeutic, psychosocial, or medical treatment in an adult day-care program that is licensed or certified by a state, or accredited to furnish adult day-care services in the--state shall not disqualify an individual from being considered to be confined to his home. Any other absence of an individual from the home shall not disqualify an individual if the absence is infrequent or

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of relatively short duration. For purposes of the preceding sentence, any absence for the purpose of attending a religious service shall be deemed to be an absence of infrequent or short duration. Also, absences from the home for non-medical purposes, such as an occasional trip to the barber, a walk around the block or a drive, would not necessarily negate the beneficiary's homebound status if the absences are undertaken on an infrequent basis and are of relatively short duration. An exception is made to the above homebound definitional criteria for beneficiaries under the age of 18 and those receiving maternity care. The only homebound criteria for these special beneficiary categories is written certification from a physician attesting to the fact that leaving the home would place the beneficiary at medical risk. In addition to the above, absences, whether regular or infrequent, from the beneficiary's primary residence for the purpose of attending an educational program in a public or private school that is licensed and/or certified by a state, shall not negate the beneficiary's homebound status.

3.3 In addition to infusion therapy provided in the home, infusion therapy may also be provided in alternative settings which include hospital outpatient departments, ambulatory infusion suites, physician's offices, or in inpatient settings.

4.0 DESCRIPTION

Infusion therapy delivered in the home may include:

- Skilled nursing services to administer the drug;
- The drug and associated compounding services; and
- Medical supplies and Durable Medical Equipment (DME).

5.0 POLICY

Coverage may be extended for infusion therapy delivered in the home when preauthorized by the Managed Care Support Contractor (MCSC). Preauthorization shall be required when:

5.1 Homebound Beneficiaries

Contractors shall ensure the following criteria are met for homebound beneficiaries receiving Home Health Care (HHC) under a Plan of Care (POC) as described in the TRICARE Reimbursement Manual (TRM), Chapter 12:

5.1.1 Homebound beneficiaries who require skilled services (e.g., skilled nursing) for administration of a home infusion drug must receive those skilled services from a Home Health Agency (HHA), in accordance with the policy described in the TRM, Chapter 12. See TRM, Chapter 2, Addendum A for beneficiary cost shares for HHC services. See TRM, Chapter 12, Section 2, Figure 12.2-1 for beneficiary cost-shares for services reimbursed outside the Home Health Agency Prospective Payment System (HHA PPS) when receiving home health services under a POC.

5.1.2 Homebound beneficiaries who desire to self-administer (or have a caregiver administer) an infusion drug obtained from a TRICARE authorized pharmacy under the TPharm contract may

do so when a physician or other authorized individual professional provider certifies that self-administration is medically appropriate. Physician or other authorized individual professional provider certification that self-administration is medically appropriate will be noted in the patient's POC described in the TRM, Chapter 12 or in the medical record.

5.1.3 The MCSC shall be responsible for beneficiary and provider education on cost-share requirements associated with infusion therapy provided in the home and cost-sharing advantages of self-administration, if self-administration is medically appropriate. See TRM, Chapter 2, Addendum A for beneficiary cost-shares for HHC services. See TRM, Chapter 2, Addendum B for beneficiary cost-shares for TPharm Benefits Program.

5.2 Non-Homebound Beneficiaries

MCSC shall provide preauthorization for non-homebound beneficiaries to receive infusion therapy in the home when:

5.2.1 Long-term infusion therapy services are needed (more than five sequential infusions). The MCSC shall preauthorize infusion therapy in the home when all of the following criteria are met:

5.2.1.1 Individual Professional Provider Certification

The attending physician certifies that the non-homebound beneficiary (or caregiver, such as a spouse) is capable and willing to learn to self-administer the infusion drug, and that self-administration in the home is medically appropriate; and

5.2.1.2 Skilled Nursing

The MCSC shall preauthorize up to five sequential skilled nursing visits (CPT[2] procedures codes 99601 and 99602) by a TRICARE authorized provider to administer and instruct the non-homebound beneficiary or caregiver to self-administer the drug. Additional visits may be authorized when medically necessary and appropriate (i.e., a change in condition requires additional visits). Claims for skilled nursing are the responsibility of the MCSC; and

5.2.1.3 Drug and Compounding Services

The MCSC shall coordinate and provide a referral to the TPharm for the drug and compounding services. If the drug is available from the TPharm, it must be provided through the TPharm Benefits Program. In the case that the drug is not available through the TPharm, the MCSC shall coordinate provision of the drug through an appropriate TRICARE authorized provider or direct the non-homebound beneficiary to care in an alternative setting; and

5.2.1.4 Medical Supplies and DME

The MCSC is responsible for ensuring the beneficiary has a referral to all medically necessary and appropriate services and supplies for infusion therapy in the home, including medical supplies and DME. Claims for medical supplies and DME are the responsibility of the MCSC;

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and

5.2.1.5 Coordination of Services

The MCSC shall coordinate delivery of infusion therapy in the home between the referring individual professional provider, the beneficiary, and necessary TRICARE authorized providers to meet the requirement of this policy of delivering care in the most medically appropriate and economical manner.

Note: See TRM, Chapter 2, Addendum A for information on beneficiary cost-shares for services of individual professional providers. See TRM, Chapter 2, Addendum B for beneficiary cost-shares for TPharm Benefits Program.

5.2.2 Short-term (five or fewer) therapy services are needed. If a non-homebound beneficiary requires five or fewer sequential infusions, the MCSC shall preauthorize up to five sequential skilled nursing visits (CPT[3] procedure codes 99601 and 99602) to administer the drug. The beneficiary is not required to learn to self-administer. The MCSC will coordinate and provide a referral for the infusion drug, DME and medical supplies in accordance with paragraphs 5.2.1.3, 5.2.1.4, and 5.2.1.5.

5.3 See Section 6.1 for coverage and policy related to medical supplies, Section 2.1 for coverage and policy related to DME, and Section 5.1 for coverage and policy related to medical devices.

5.4 See the TRM, Chapter 3, Section 6 for information on the processing and payment of home infusion claims for home-based services provided by Corporate Service Providers (CSPs), and the TRM, Chapter 1, Section 15 for information on legend drugs and insulin reimbursement.

5.5 See Section 9.1 for information on the Pharmacy Benefits Program.

5.6 Provider payments are reduced for the failure to comply with the preauthorization requirements in this section. See TRM, Chapter 1, Section 28.

6.0 EXCEPTIONS

In the event that a non-homebound beneficiary: (1) is unable or unwilling to learn to self-administer and requires skilled services to administer the infusion drug; (2) requires long-term infusion therapy; and (3) infusion therapy in the home is requested and is medically appropriate, the MCSC shall preauthorize infusion therapy in the home when it is determined that infusion in the home setting, provided in the same manner as described in paragraph 5.2.2 without the limit of five visits, is less costly to the government than infusion in an alternative setting.

7.0 EXCLUSIONS

7.1 "S" codes, except those described in Chapter 1, Section 13.1.

7.2 Long-term infusion therapy in the home for non-homebound beneficiaries who are unwilling to learn to self-administer.

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7.3 TRICARE dual eligible beneficiaries are not subject to the requirements in this policy.

7.4 TRICARE Overseas Program (TOP) beneficiaries are not subject to the requirements of this policy.

7.5 Beneficiaries with Other Health Insurance (OHI), where TRICARE is not the primary payor, are not subject to the requirements of this policy.

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