Select Health Medical Policies

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Select Health

MEDICAL POLICY

COVERAGE WITH EVIDENCE DEVELOPMENT

Policy # 616
Implementation Date:9/1/17
Review Dates: 2/5/19, 2/18/20, 2/16/21, 1/20/22, 2/15/23, 2/20/24, 2/14/25
Revision Dates:

Related Medical Policies:

#138 Investigational Trial Coverage
#332 Investigational Device Exemption (Category A & B)
#88 In-Network Coverage of Medical Services with an Out-of-Network Provider

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Coverage with Evidence Development (CED) is a paradigm whereby Medicare covers items and services on the condition that they are furnished in the context of approved clinical studies or with the collection of additional clinical data. The purpose of CED is to generate data on the utilization and impact of the item or service evaluated in the NCD, so that Medicare can a) document the appropriateness of use of that item or service in Medicare beneficiaries under current coverage; b) consider future changes in coverage for the item or service; c) generate clinical information that will improve the evidence base on which providers base their recommendations to Medicare beneficiaries regarding the item or service.

In making coverage decisions involving CED, CMS (Centers for Medicare and Medicaid Services) decides after a formal review of the medical literature to cover an item or service only in the context of an approved clinical study or when additional clinical data are collected to assess the appropriateness of an item or service for use with a particular beneficiary.

Although Medicare generally does not cover experimental or investigational items and services as reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act (and regulations at 42 CFR 411.15(o)), the Medicare program has adopted coverage policies that relate to clinical studies before the formal articulation in 2006 of the CED paradigm. In 1995, CMS (then known as the Health Care Financing Administration (HCFA)) established coverage for certain items furnished in FDA-approved IDE trials (42 CFR 405 Subpart B). CMS updated the coverage criteria for certain items and services in IDE trials effective January 1, 2015 (78 FR 74429-74437). In response to a June 7, 2000 Executive Memorandum, CMS (then HCFA) issued an NCD for coverage under the authority of section 1862(a)(1)(E) of routine costs in clinical trials, commonly referred to as the Clinical Trial Policy (Section 310.1 of the NCD Manual). The Clinical Trial Policy was revised in 2007 through the NCD reconsideration process.

Subsequently, CMS issued guidance on the CED paradigm in the 2006 guidance document entitled National Coverage Determinations with Data Collection as a Condition of Coverage: Coverage with Evidence Development. The 2006 document introduced two arms of CED which included Clinical Study Participation (CSP) and Coverage with Appropriateness Determination (CAD). While the concepts behind both arms are described in this document, CMS no longer uses this terminology to distinguish the two.

CMS has issued 27 NCDs requiring CEDs over the last two decades to provide Medicare beneficiary access to promising items and services that could not otherwise be covered under section 1862(a)(1)(A) of the Act. CMS has approved >120 CED studies and 5 national registries to facilitate evidence development for these CED NCDs. Forty-two of these studies have generated evidence across 14 topics

Coverage with Evidence Development, continued

covered under CED. Three CED NCD topics have had the CED requirement removed following an NCD reconsideration and have received national coverage.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers technologies meeting CMS requirements for evidence in development, including both sub-types of CED referred to Coverage with Appropriateness Determination (CAD) and Coverage with Study Participation (CSP), when the following general guidelines are met.

General Guidelines Requirements for Coverage with Evidence (ALL must be met).

1. The principal purpose of the study is to test whether the item or service meaningfully improves health outcomes of affected beneficiaries who are represented by the enrolled subjects.
2. The rationale for the study is well supported by available scientific and medical evidence.
3. The study results are not anticipated to unjustifiably duplicate existing knowledge.
4. The study design is methodologically appropriate, and the anticipated number of enrolled subjects is sufficient to answer the research question(s) being asked in the National Coverage Determination.
5. The study is sponsored by an organization or individual capable of completing it successfully.
6. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found in the Code of Federal Regulations (CFR) at 45 CFR Part 46. If a study is regulated by the Food and Drug Administration (FDA), it is also in compliance with 21 CFR Parts 50 and 56. In addition, to further enhance the protection of human subjects in studies conducted under CED, the study must provide and obtain meaningful informed consent from patients regarding the risks associated with the study items and/or services, and the use and eventual disposition of the collected data.
7. All aspects of the study are conducted according to appropriate standards of scientific integrity.
8. The study has a written protocol that clearly demonstrates adherence to the standards listed here as Medicare requirements.
9. The study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Such studies may meet this requirement only if the disease or condition being studied is life threatening as defined in 21 CFR §312.81(a) and the patient has no other viable treatment options.
10. The clinical research studies and registries are registered on the www.ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject. Registries are also registered in the Agency for Healthcare Quality (AHRQ) Registry of Patient Registries (RoPR).
11. The research study protocol specifies the method and timing of public release of all prespecified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 12 months of the study's primary completion date, which is the date the final subject had final data collection for the primary endpoint, even if the trial does not achieve its primary aim. The results must include number started/completed, summary results for primary and secondary outcome measures, statistical analyses, and adverse events. Final results must be reported in a publicly accessibly manner; either in a peer-reviewed scientific journal (in print or online), in an online publicly accessible registry dedicated to the dissemination of clinical trial information such as ClinicalTrials.gov, or in journals willing to publish in abbreviated format (e.g., for studies with negative or incomplete results).

Coverage with Evidence Development, continued

12. The study protocol must explicitly discuss beneficiary subpopulations affected by the item or service under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and a plan for the retention and reporting of said populations in the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.
13. The study protocol explicitly discusses how the results are or are not expected to be generalizable to affected beneficiary subpopulations. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability, or Medicaid eligibility.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

When making national coverage determinations, CMS evaluates relevant clinical evidence to determine whether the evidence is of sufficient quality to support a finding that an item or service that falls within a benefit category is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. This critical appraisal of the evidence enables us to determine whether: 1) assessment questions specific to the process of the evidence evaluation can be answered conclusively; and 2) the investigational item or service will improve health outcomes for patients. An improved health outcome is one of several considerations in determining whether an item or service is reasonable and necessary.

When CMS assesses the clinical evidence of an item or service, we take the following three factors into account: 1) the quality of the individual studies; 2) the relevance of findings from individual studies to the Medicare population; and 3) overarching conclusions that can be drawn from the body of the evidence about the direction and magnitude of the risks and benefits of the item or service under investigation.

V. Coverage with Evidence Development

A. Coverage with Appropriateness Determination (CAD)

If the evidence for an item or service being evaluated is adequate to determine that the item or service is reasonable and necessary under section 1862(a)(1)(A), CMS may determine that the item is covered under Medicare. Given the importance of the patient's factual circumstances in determining the appropriate treatment, coverage without conditions is rare. Most NCDs have restrictions that ensure that appropriate patients are receiving care by competent providers. CMS may have concerns that beneficiaries receiving the item or service meet the conditions specified in the NCD. In these cases, CMS could require CAD, which allows CMS to ensure that new technology is provided appropriately to patients meeting specific characteristics as described in the NCD.

In the application of CAD, CMS may decide that there is adequate evidence to determine that an item or service is reasonable and necessary under section 1862(a)(1)(A), but that additional clinical data is needed that is not routinely available on claims forms to ensure that the item or

service is being provided to appropriate patients in the manner described in the NCD. The extra data supplements the information gathered routinely through claims for services rendered and is collected by providers when the service is provided. For the most part, providers will submit extra data to databases or registries specifically designed for collecting data specified in the NCD in question. Our agreements with entities establishing the registries will include protections to ensure that Medicare health information is protected.

CAD will only be invoked when there is adequate evidence to determine that the item or service is to be covered. However, when an NCD requires CAD, only items or services for patients who are included in the data collection are covered. CAD will be required when CMS is concerned that the data collected on a claims form is insufficient to determine that the item or service was appropriately provided as outlined in the NCD. The following are some concerns that may lead to a coverage decision that requires CAD as a condition of coverage:

1. If the newly covered item or service should be restricted to patients with specific conditions and criteria.
2. If the newly covered item or service should be restricted for use by providers with specific training or credentials.
3. If there is concern among clinical thought leaders that there are substantial opportunities for misuse of the item or service.
4. If the coverage determination significantly changes how providers manage patients utilizing this newly covered item or service.

CMS does not intend to routinely develop, oversee, or maintain these databases or registries that contain information about provision of an item or service. However, CMS will only accept data from registries that conform to accepted standards to ensure that the data collected is sufficient to determine if the item or service is reasonable and necessary for Medicare coverage under section 1862(a)(1)(A). In particular, the registries must have qualified scientific oversight; tested and validated data collection methods; adequate patient safety and monitoring; quality assurance and data protection; and appropriate human subjects protections.

B. Coverage with Study Participation (CSP)

CSP will allow coverage of certain items or services for which the evidence is not adequate to support coverage under section 1862(a)(1)(A) and where additional data gathered in the context of clinical care would further clarify the impact of these items and services on the health of Medicare beneficiaries. In the past, this level of evidence would have prompted non-coverage decisions.

CSP allows CMS to determine that an item or service is only reasonable and necessary when it is provided within a research setting where there are added safety, patient protections, monitoring, and clinical expertise. If CMS decides that there is limited existing evidence to support a decision to cover the item or service under review and more evidence is needed for CMS to determine whether that item or service meets the evidentiary standards for reasonable and necessary, then the item or service is found to not be reasonable and necessary for Medicare coverage under section 1862(a)(1)(A). CMS may then consider whether coverage of the item or service is reasonable and necessary for Medicare coverage under section 1862(a)(1)(E)4 of the Act.

This section states:

(a) Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services—

(E) in the case of research conducted pursuant to section 1142, which is not reasonable and necessary to carry out the purposes of that section,

Section 1142 describes the authority of the Agency for Healthcare Research and Quality (AHRQ). As part of section 1142, AHRQ assures that research priorities appropriately reflect the needs and priorities of the Medicare program under Title XVIII, as set forth by the CMS Administrator.

Using section 1862(a)(1)(E) authority, the CED/CSP concept considers the item or service to be reasonable and necessary only while evidence is being developed. Under section 1142, research may be conducted on the outcomes, effectiveness, and appropriateness of healthcare services and

Coverage with Evidence Development, continued

procedures to identify the way diseases, disorders, and other health conditions can be prevented, diagnosed, treated, and managed clinically.

In addition, evaluations of the comparative effects, health and functional capacity; alternative services and procedures utilized in preventing, diagnosing, treating, and clinically managing diseases, disorders, and other health conditions may be conducted.

When the evidence is inadequate to determine that the item or service is reasonable and necessary under section 1862(a)(1)(A), Medicare coverage may be extended to patients enrolled in a clinical research study. In this case, the research is conducted under section 1862(a)(1)(E). The following list includes some of the evidentiary findings that might result in CMS issuing an NCD for items and services that do not have sufficient evidence for coverage under section 1862(a)(1)(A) that would provide payment only for Medicare patients enrolled in a research study:

1. Available evidence may be a product of otherwise methodologically rigorous evaluations but may not have evaluated outcomes that are relevant to Medicare beneficiaries.
2. The available clinical research may have failed to address adequately the risks and benefits to Medicare beneficiaries for off-label or other unanticipated uses of a drug, biologic, service or device.
3. Available clinical research studies may not have included specific patient subgroups or patients with disease characteristics that are highly prevalent in the Medicare population.
4. New applications may exist for diagnostic services and devices that are already on the market, but there is little or no published research that supports a determination of reasonable and necessary for Medicare coverage at the time of the request for an NCD.
5. Sufficient evidence about the health benefits of a given item or service to support a reasonable and necessary determination is available only for a subgroup of Medicare patients with specific clinical criteria and/or for providers with certain experience or other qualifications. Other patient subgroups or providers require additional evidence to determine if the item or service is reasonable and necessary.

CSP research conducted may include a broader range of studies than randomized clinical trials to include observational research. However, all studies must conform to the standards that will be developed by the Clinical Research Policy.

In rare instances, for some items or services, CMS may determine that the evidence is very preliminary and not reasonable and necessary for Medicare coverage under section 1862(a)(1)(A), but, if the following criteria are met, CSP might be appropriate:

a. The evidence includes assurance of basic safety;

b. The item or service has a high potential to provide significant benefit to Medicare beneficiaries; and

c. There are significant barriers to conducting clinical trials.

These research studies will be rigorously designed and meet standards to be developed in a reconsideration of the current Clinical Trial Policy established under a 2000 NCD.

New evidence that assists in the Medicare coverage process for the item or service is one of the desired results of CSP. However, a more important outcome is the production of evidence that will influence clinical practice and help Medicare beneficiaries and providers make the most appropriate diagnostic and therapeutic decisions. If the research results are published in a peer-reviewed journal, the evidence will be used in an NCD reconsideration to determine if a change in Medicare coverage is appropriate under section 1862(a)(1)(A).

If CMS determines that the evidence for coverage of certain items or services is inadequate to establish Medicare coverage under 1862(a)(1)(A), Medicare may still reimburse for that item or service for Medicare beneficiaries enrolled in a research study that provides data and information to be used to evaluate that item or service, as well as reimburse for the routine costs incurred by Medicare beneficiaries in the study.

Coverage with Evidence Development, continued

To qualify for reimbursement, such a study must be designed to produce evidence that could be used in a future national coverage decision that would focus on whether the item or service should be covered by Medicare under 1862(a)(1)(A). Payment for the items and services provided in the study will be restricted to the Medicare qualified patients involved as human subjects in the study.

CMS will only provide payment for clinical research that meets the standards of a qualified trial as will be outlined in the revision of the Clinical Trial Policy. We anticipate this NCD will include the following principles:

1. The primary purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes.
2. The trial is well-supported by available scientific and medical information or is intended to clarify or establish the health outcomes of interventions already in common clinical use.
3. The trial does not duplicate existing studies unjustifiably.
4. The trial design is appropriate to answer the research question being asked in the trial.
5. The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully.
6. The trial follows federal regulations relating to the protection of human subjects.
7. All aspects of the trial are conducted according to the appropriate standards of scientific integrity.
8. The trial is listed in the National Library of Medicine clinical trials database.
9. The sample of study subjects in the trial should include individuals who are representative of the Medicare population, with the condition described in the NCD.

Coverage of Control Groups in CED Studies under 1862(a)(1)(E): Standard of Care and Placebo controls; and Blinding or Masking: In the most rigorous experimental designs, a new treatment is compared to something else for purposes of studying effectiveness and to control for the placebo effect or other observation biases. For example, a carotid stent procedure may be compared to the current best standard of medical care; in a drug trial, some subjects may be randomized to receive a placebo medication; or to study an orthopedic procedure for back pain, the control group may be randomized to receive a placebo procedure to preserve blinding. The purpose of a placebo control group is to account for the placebo effect; that is, to exclude from the study certain effects that do not depend on the treatment itself. Such factors can include participants' knowledge that they are receiving a treatment and receiving extra attention from healthcare professionals, and the expectations of a treatment's effectiveness by those running the research study. Without a placebo group to compare against, it is not possible to know or measure the effect of the treatment itself. These methods effectively blind or mask patients and investigators, if the trial is double blinded, to their treatment assignment. Placebo controls can be critical in evaluating endpoints that may be vulnerable to subjective interpretation, such as changes in pain levels or depression.

While the items and services furnished as placebo controls may not be considered reasonable and necessary under section 1862(a)(1)(A) of the statute because they have no health benefit, these items and services can be necessary in order to conduct a scientifically valid clinical study. As such, these services can be covered under section 1862(a)(1)(E) when furnished in the context of a clinical study where coverage is necessary to preserve the scientific integrity of the study.

In section 184 of the Medicare Improvements for Patients and Providers of 2008 (MIPPA), Congress added a new subsection 1833(w) of the Act which allows the Secretary to develop alternative methods of payment under Medicare Part B for items and services provided under clinical trials and comparative effectiveness studies sponsored or supported by an agency of the Department of Health & Human Services: "… to the extent such alternative methods are necessary to preserve the scientific validity of such trials or studies, such as in the case where masking the identity of interventions from patients and investigators is necessary to comply with the particular trial or study design." We may use this authority, for example, to ensure that a placebo control group is not undermined by differences in Medicare payment methods that would otherwise reveal the group to which a patient has been assigned.

Coverage with Evidence Development, continued

Under CED, routine costs of an approved clinical trial in both the treatment arm and the control (standard of care or placebo) arm are paid. Routine costs include all items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a benefit, coverage is not statutorily excluded, and there is not a national non-coverage decision) that are provided in either the experimental or the control arms of a clinical trial.

Billing/Coding Information

CPT CODES

Too numerous to list

HCPCS CODES

Too numerous to list

Key References

1. Guidance for the Public, Industry, and CMS Staff Coverage with Evidence Development Document Issued on November 20, 2014. https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?MCDId=27. Accessed 20 Feb 24.
2. https://www.cms.gov/medicare/coverage/evidence
3. https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?mcdid=38
4. Medicare's Coverage With Evidence Development: A Policy-Making Tool in Evolution. *J Oncol Pract*. 2007 Nov;3(6):296-301.
5. Medicare Managed Care Manual, Chapter 4, Section 10.7.2 – Payment for Investigational Device Exemption (IDE) Studies at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c04.pdf. Accessed 11feb25.
6. Medicare Managed Care Manual, Chapter 4, Section 10.7.3 – Payment for Clinical Studies Approved under Coverage with Evidence at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c04.pdf.) Accessed 11feb25
7. Medicare Benefit Policy Manual, Chapter 14, Section 20 - Food and Drug Administration (FDA)-Approved Investigational Device Exemption (IDE) Studies at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c14.pdf.
8. Social Security Act §1862(a)(1)(A). Accessed 20 Feb 24.
9. Zeitler, E. P. & Gilstrap, L. G. Coverage With Evidence Development: Where Are We Now? *The American Journal of Managed Care*. 2022;28(8):382-389. https: doi.org/10.37765/ajmc.2022.88870
10. §1869(f) of the Social Security Act; 42 CFR Part 426.
11. §1142(a)(1)(A) of the Social Security Act.

Disclaimer

This document is for informational purposes only and should not be relied on in the diagnosis and care of individual patients. Medical and Coding/Reimbursement policies do not constitute medical advice, plan preauthorization, certification, an explanation of benefits, or a contract. Members should consult with appropriate healthcare providers to obtain needed medical advice, care, and treatment. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the member's individual benefit plan that is in effect at the time services are rendered.

The codes for treatments and procedures applicable to this policy are included for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Select Health® makes no representations and accepts no liability with respect to the content of any external information cited or relied upon in this policy. Select Health updates its Coverage Policies regularly, and reserves the right to amend these policies without notice to healthcare providers or Select Health members.

Members may contact Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Coverage Policy may call Select Health Provider Relations at (801) 442-3692.

Select Health

MEDICAL POLICY

INVESTIGATIONAL DEVICE EXEMPTION (CATEGORY A & B)

Policy # 332

Implementation Date: 11/15/06

Review Dates: 12/20/07, 12/18/08, 10/21/10, 10/13/11, 7/18/13, 6/19/14, 6/11/15, 6/16/16, 10/20/16, 6/15/17, 7/16/18, 6/20/19, 6/17/20, 6/17/21, 5/18/22, 6/13/23, 6/13/24

Revision Dates: 12/17/09

Related Medical Policies:

#138 Investigational Trial Coverage

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

An investigational device exemption (IDE) allows an investigational device to be used in a clinical study to collect safety and effectiveness data required to support a Premarket Approval (PMA) application or a Premarket Notification [510(k)] submission to the FDA. Clinical studies are most often conducted to support a PMA. Only a small percentage of 510(k)s require clinical data to support the application. Investigational use also includes clinical evaluation of certain modifications or new intended uses of legally marketed devices. All clinical evaluations of investigational devices, unless exempt, must have an approved IDE before the study is initiated.

An approved IDE permits a device to be shipped lawfully for the purpose of conducting investigations of the device without complying with other requirements of the Food, Drug, and Cosmetic Act (FDCA) that would apply to devices in commercial distribution. Sponsors need not submit a PMA or Premarket Notification 510(k), register their establishment, or list the device while the device is under investigation. Sponsors of IDEs are also exempt from the Quality System (QS) Regulation except for the requirements for design control.

In addition, all IDE devices must be classified into one of three regulatory classes: Class I (general controls), Class II (special controls), or Class III (premarket approval). For the purposes of consideration for reimbursement under the Medicare program, the FDA has categorized all FDA-approved IDEs into either Category A (experimental/investigational) or Category B (nonexperimental/investigational).

An experimental/investigational (Category A) device refers to an innovative device believed to be in Class III for which "absolute risk" of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved, and the FDA is unsure whether the device type can be safe and effective). A nonexperimental/investigational (Category B) device refers to a device believed to be in Class I or Class II, or a device believed to be in Class III for which the incremental risk is the primary risk in question (that is, underlying questions of safety and effectiveness of the device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers Category B investigational devices in limited circumstances.

Investigational Device Exemption, continued

Requirements for Category B IDE device coverage (must meet all the following):

1. Device has attained Category B FDA status; and
2. Device is being used as part of an investigational study as part of an FDA PMA application; and
3. Investigational study has been approved by an Institutional Review Board (IRB) approved by Intermountain Health; and
4. Device is being used by a participating Select Health provider; and
5. If use in a hospital setting is required, the device must be administered at a contracted facility; and
6. Select Health will evaluate possible safety concerns to determine if adequate data exists that supports the safety or efficacy of the device.

Select Health does NOT cover Category A investigational devices as these devices meet the plan's definition of experimental/investigational.

SELECT HEALTH ADVANTAGE (MEDICARE/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information
On November 1, 1995, the Centers for Medicare and Medicaid Services (CMS) and the FDA established a policy as a more precise mechanism for classifying devices undergoing clinical trials that make it possible for certain devices to be eligible for Medicare coverage. The new policy allowed for a distinction to be made among devices subject to pre-market approval, to separate devices that can be considered for Medicare payment, and those that are truly experimental. Two categories have been developed to classify devices under IDEs: Category A (experimental) and Category B (nonexperimental/investigational).

Category A devices are novel, first-of-a-kind technologies. They are innovative devices for which the absolute risk of the device type has not been established and initial questions of safety and effectiveness have not been resolved. The FDA is unsure whether these device types can be safe and effective.

Category B devices are newer generations of proven technologies, initial questions of safety and effectiveness of these devices have been resolved, and devices placed in this category are considered to represent evolutionary changes in proven technologies.

The FDA approved IDE study protocols restrict investigational device shipment to a limited number of investigational sites for testing on a specific number of patients. To the extent Medicare covers a Category B device; coverage is limited to beneficiaries meeting the protocol requirements. For example, coverage of an investigational device may be limited to Medicare beneficiaries participating in trials conducted by certain healthcare practitioners in an approved clinical trial.

Investigational Device Exemption, continued

Billing/Coding Information

CPT CODES

No specific codes identified

HCPCS CODES

No specific codes identified

Key References

1. Centers for Medicare & Medicaid Services. "Medicare Benefit Policy Manual: Chapter 14 – Medical Devices. Human & Health Services. Available at: http://www.cms.hhs.gov/manuals/Downloads/bp102c14.pdf. Date accessed: 12/16/09.
2. Food and Drug Administration. "Overview of Device Regulation." Available at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm. Date accessed: 12/16/09.
3. http://www.fda.gov/cdrh/ode/idepolcy.pdf Guidance on IDE Policies and Procedures

Select Health

Select Health

MEDICAL POLICY

INVESTIGATIONAL TRIAL COVERAGE

Policy # 138

Implementation Date:8/27/02

Review Dates: 10/23/03, 11/18/04, 12/21/06, 12/20/07, 12/18/08, 12/17/09, 10/21/10, 10/13/11, 7/18/13, 6/19/14, 3/19/15, 10/20/16, 10/19/17, 10/15/18, 10/16/19, 10/15/20, 11/18/21, 9/15/22, 10/13/23, 10/14/24

Revision Dates: 4/7/03, 1/1/14, 5/1/15, 2/3/20

Related Medical Policies:

#332 Investigational Device Exemption (Category A & B)

#88 In-Network Coverage of Medical Services with an Out-of-Network Provider

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (Medicare), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Many technologies have been "approved" in recent years by government agencies without establishing their definitive benefit to the population. The fact that these interventions, whether procedural, technical, or therapeutic, have been approved by federally recognized government bodies, often leads to conflict between payers and patients/subscribers and physicians. Additionally, many of these procedures/therapeutic innovations are supported by literature, that, though not conclusive, support some possible clinical benefit. Consequently, it is in the best interest of Select Health to support such research for the benefit of its subscribers.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers "Routine Patient Costs" incurred by a "Qualifying Individual" who is participating in an "Approved Clinical Trial" for non-grandfathered health plans.

Benefits include the reasonable and necessary items and services used to prevent, diagnose, and treat complications arising from participation in a qualifying clinical trial.

Benefits are available only when the Covered Person is clinically eligible for participation in the qualifying clinical trial as defined by the researcher.

I. Definitions (For Idaho Commercial, Fully-Insured plans, see criteria below**)

1. "Approved Clinical Trials" are only considered in one of the following circumstances:
   a. Phase I, Phase II, Phase III, or Phase IV clinical trial,
   b. Being conducted in relation to the prevention, detection, or treatment of cancer, or other life-threatening disease or condition, **and**
   c. Meets the requirements under Section II below.
2. "Life-threatening disease or condition" is one from which the likelihood of death is probable unless the course of the disease or condition is interrupted.

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3. "Routine Patient Costs*" include all items and services consistent with the coverage provided in the plan that is typically covered for a qualified individual who is not enrolled in a clinical trial. (e.g., office visits, lab tests, supportive care drugs, procedures and services needed during a trial)

   *Routine patient costs do not include:

   1. The investigational item, device, or service itself;
   2. Items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient; **and**
   3. A service that is clearly inconsistent with the widely accepted and established standards of care for a particular diagnosis.

II. CRITERIA FOR APPROVED CLINICAL TRIALS

A. The clinical trial must be described in paragraph 1, 2, or 3 below.

1. Federally funded trials. The study or investigation is approved or funded (which may include funding through in-kind contributions) by one or more of the following:
   a. *National Institutes of Health (NIH)*. (Includes *National Cancer Institute (NCI)*.)
   b. *Centers for Disease Control and Prevention (CDC)*.
   c. *Agency for Healthcare Research and Quality (AHRQ)*.
   d. *Centers for Medicare and Medicaid Services (CMS)*.
   e. A cooperative group or center of any of the entities described above or the *Department of Defense (DOD)* or the *Veterans Administration (VA).*
   f. A qualified non-governmental research entity identified in the guidelines issued by the *National Institutes of Health* for center support grants.
   g. The *Department of Veterans Affairs*, the *Department of Defense*, or the *Department of Energy*, if the study or investigation has been reviewed and approved through a system of peer review that is determined by the *Secretary of Health and Human Services* to meet both of the following criteria:
      i. Comparable to the system of peer review of studies and investigations used by the *National Institutes of Health*.
      ii. Ensures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.
2. The study or investigation is conducted under an investigational new drug (IND) application reviewed by the *U.S. Food and Drug Administration*.
3. The study or investigation is a drug trial that is exempt from having such an investigational new drug application.

   (**Idaho Commercial, Fully-Insured plans do not require a disease or condition to be 'life-threatening' to qualify for Investigational Trial Coverage. A study or investigation does not have to be 'new' to qualify; if the study or investigation has been reviewed and approved by the institution review board (IRB) that has an agreement with the Office for Human Research Protections of the United States Department of Health and Human Services, it is eligible.)

B. **Additional Requirements**

1. The clinical trial must have a written protocol that describes a scientifically sound study and have been approved by all relevant institutional review boards (*IRBs*) before participants are enrolled in the trial. We may, at any time, request documentation about the trial.
2. The subject or purpose of the trial must be the evaluation of an item or service that meets the definition of a Covered Health Service and is not otherwise excluded under the Policy.

III. **QUALIFIED INDIVIDUAL**

A. To be a qualified individual, an individual must be:

1. Covered under the health plan, and
2. Eligible to participate in an approved clinical trial according to the trial protocol based upon:
   - The individual was referred to the clinical trial by an in-network healthcare professional who has concluded that the individual's participation would be appropriate because the individual is eligible for the trial according to its protocol, **or**
   - The individual provides the plan with medical and scientific information that establishes that participation would be appropriate because the individual is eligible for the trial according to its protocol.

Network Plans: If one or more network providers are participating in a clinical trial, then Select Health will require that the Qualified Individual participate in the clinical trial using a network provider, if the network provider will accept the qualifying individual as a participant in the trial. However, if an Approved Clinical Trial is conducted outside of the Qualified Individual's state of residence, then Select Health may deny, or otherwise limit payment for Routine Patient Services, solely on the basis that the trial is conducted out-of-state.

COVERAGE LIMITATIONS AND EXCLUSIONS:

BENEFITS FOR CLINICAL TRIALS DO NOT INCLUDE:

A. The Experimental or Investigational Service or item that is used in the clinical trial is not covered, except for the following:
   1. Certain *Category B* devices (see definition below)
   2. Certain promising interventions for patients with terminal illnesses.
   3. Other items and services that, in Select Health's determination, meet specified criteria in accordance with Select Health's medical and drug policies.

B. Items and services provided solely to satisfy data collection and analysis needs, and that are not used in the direct clinical management of the patient. Examples include, but are not limited to:
   1. Laboratory tests and imaging studies done at a frequency dictated by the study protocol and not consistent with signs and symptoms and other standards of care for that diagnosis or treatment type.

C. A service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis.

D. Items and services provided by the research sponsors free of charge for any person enrolled in the trial.

E. Travel and transportation expenses are excluded from coverage. These include, but are not limited to, the following examples:
   1. Fees for all types of transportation. Examples include, but are not limited to: personal vehicle, taxi, medical van, ambulance, commercial airline, and train.
   2. Rental car expenses.
   3. Mileage reimbursement for driving a personal vehicle.
   4. Lodging.
   5. Meals.

F. Routine patient costs obtained out-of-network where non-network benefits do not exist under the plan.

Investigational Trial Coverage, continued

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Billing/Coding Information

CPT CODES

Applicable Modifiers

Q0	Investigational clinical service provided in a clinical research study that is in an approved clinical research study.
Q1	Routine clinical service provided in a clinical research study that is in an approved clinical research study.

HCPCS CODES

These Codes may be covered if criteria are met:

S9988	Services provided as part of a Phase I Clinical Trial
S9990	Services provided as part of a Phase II Clinical Trial
S9991	Services provided as part of a Phase III Clinical Trial
G0293	Noncovered surgical procedure(s) using conscious sedation, regional, general or spinal anesthesia in a Medicare qualifying Clinical Trial, per day
G0294	Noncovered procedure(s) using either no anesthesia or local anesthesia only, in a Medicare qualifying clinical trial, per day

These codes are not covered

G9057	Oncology; practice guidelines; management differs from guidelines as a result of patient enrollment in an institutional review board approved clinical trial (for use in a medicare-approved demonstration project)
S9992	Transportation costs to and from trial location and local transportation costs (e.g., fares for taxicab or bus) for clinical trial participant and one caregiver/companion
S9994	Lodging costs (e.g., hotel charges) for clinical trial participant and one caregiver/companion

Key References

1. Medicare Benefit Policy Manual, Chapter 14 - Medical Devices. § 20.2 Category B; available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c14.pdf
2. Medicare Transmittal 126, September 19, 2000, new section 30-1: http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R126CIM.pdf
3. NCD for Routine Costs in Clinical Trials, Section 310.1, Publication 100-3 @ http://www.cms.gov/medicare-coverage-database/indexes/ncd-alphabetical-index.aspx?bc=AgAAAAAAAAAAAA%3d%3d&
4. US Department of Health and Human Services, Healthcare.gov Health Care Law information page: http://www.healthcare.gov/law/index.html
5. US National Institutes of Health, Learn About Clinical Studies information page: http://clinicaltrials.gov/ct2/info/understand

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Investigational Trial Coverage, continued

Disclaimer
This document is for informational purposes only and should not be relied on in the diagnosis and care of individual patients. Medical and Coding/Reimbursement policies do not constitute medical advice, plan preauthorization, certification, an explanation of benefits, or a contract. Members should consult with appropriate healthcare providers to obtain needed medical advice, care, and treatment. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the member's individual benefit plan that is in effect at the time services are rendered.

The codes for treatments and procedures applicable to this policy are included for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Select Health® makes no representations and accepts no liability with respect to the content of any external information cited or relied upon in this policy. Select Health updates its Coverage Policies regularly, and reserves the right to amend these policies without notice to healthcare providers or Select Health members.

Members may contact Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Coverage Policy may call Select Health Provider Relations at (801) 442-3692.

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MEDICAL POLICY

MEDICAL NECESSITY

Policy # 148

Implementation Date:10/1/02

Review Dates: 12/2/02, 2/26/04, 1/13/05, 12/20/07, 12/18/08, 12/17/09, 10/21/10, 10/13/11, 7/18/13, 6/19/14, 6/11/15, 6/16/16, 6/15/17, 2/18/19, 2/17/20, 2/16/21, 1/18/22, 2/10/23, 2/23/24, 2/25/25

Revision Dates: 12/9/02, 9/14/06

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

As a health insurer in the state of Utah, Select Health must abide by rules established by the State Insurance Commission applicable to HMOs. Additionally, Select Health desires to provide appropriate services to members who meet these guidelines. Thus, Select Health policies and decisions are designed to adhere to the definition of "medical necessity" established according to Utah State Rules.

Utah State Rules define "**medical necessity**" as follows:

1. Health care services or products that a prudent health care professional would provide to a patient for the purpose of preventing, diagnosing or treating an illness, injury, disease or its symptoms in a manner that is:
   a) In accordance with generally accepted standards of medical practice in the United States;
   b) Clinically appropriate in terms of type, frequency, extent, site, and duration;
   c) Not primarily for the convenience of the patient, physician, or other health care provider; and
   d) Covered under the contract; and
2. When a medical question-of-fact exists, medical necessity shall include the most appropriate available supply or level of service for the individual in question, considering potential benefits and harms to the individual, and known to be effective.
   a) For interventions not yet in widespread use, the effectiveness shall be based on scientific evidence.
   b) For established interventions, the effectiveness shall be based on:
      - Scientific evidence;
      - Professional standards; and
      - Expert opinion.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health covers medically necessary services consistent with Utah State Rule R590-233-3 (17) unless such services are specifically excluded by contract.

Medical Necessity, continued

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website https://www.cms.gov/medicare-coverage-database/search.aspx?redirect=Y&from=Overview&from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website https://medicaid.utah.gov/utah-medicaid-official-publications/ or the Utah Medicaid code Look-Up tool

Key References

1. Utah State Rule R590-203. Health Grievance Review Process
2. Utah State Rule R590-233-3 (17). Health Benefit Plan Insurance Standards

Disclaimer

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The codes for treatments and procedures applicable to this policy are included for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Select Health® makes no representations and accepts no liability with respect to the content of any external information cited or relied upon in this policy. Select Health updates its Coverage Policies regularly, and reserves the right to amend these policies without notice to healthcare providers or Select Health members.

Members may contact Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Coverage Policy may call Select Health Provider Relations at (801) 442-3692.

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MEDICAL POLICY

PRIVATE DUTY NURSING

Policy # 169

Implementation Date: 5/12/03

Review Dates: 4/22/04, 4/14/05, 10/18/07, 10/23/08, 10/22/09, 4/21/11, 4/12/12, 10/24/13, 10/23/14, 10/15/15, 10/20/16, 10/19/17, 10/18/18, 10/15/19, 9/29/20, 11/4/21, 9/12/22, 10/18/23, 9/29/24

Revision Dates: 5/12/03, 9/21/06, 12/31/12, 10/19/17, 10/23/24

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Advantage (Medicare/CMS), and Select Health Community Care (Medicaid/CHIP) plans. Refer to the "Policy" section for more information.

Description

Private duty nursing (PDN) involves the provision of care to health plan members in a home environment. This function is for a defined timeframe throughout a 24-hour period. The intent of private duty services is to provide a bridge between care provided in a hospital setting and the home environment. During this transition of care, private duty nursing is utilized to perform skilled nursing functions. As private duty nursing is intended to provide transitional care for plan members, it is only provided for a defined period, usually not to exceed 3 months, so that family members can be trained to perform the functions requiring the presence of nursing services.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers private duty nursing (PDN) for the acute transition from an inpatient setting to home in *limited* circumstances.

Criteria for coverage:

1. The patient is under active case management with Select Health;
2. The member is either ventilator or tracheostomy dependent;
3. The member meets InterQual guidelines for SNF;
4. The primary care physician or specialist has agreed to the home care plan;
5. Placement of the nurse is for the care and benefit of the member with a skilled need only;
6. The member and family acknowledge that this service is temporary as a transition to an alternative care environment.

The goal of the private duty nursing is to have the patient transitioned off the nursing service within 3 months of the admission to home care. Coverage will be provided based on the following:

Diagnosis:	Family Caregivers	Baseline Hrs.	Max. Hrs.
Ventilator Dependent	2	8–10	12
Ventilator Dependent	1	10–12	14
Tracheostomy Dependent	2	6–8	10
Tracheostomy Dependent	1	8–10	12

Maximum hours are to be used only on a PRN basis when acute exacerbations of illnesses occur and require a short-term, temporary increase in skilled needs in the home.

Private Duty Nursing, continued

Exceptions to the limitations of coverage may be considered on a case-by-case basis for temporary increases in coverage, which may prevent acute hospitalization or temporary extensions to cover a short-term gap. This service should not exceed a 2-week period.

SELECT HEALTH ADVANTAGE (MEDICARE/CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the Select Health Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

Private duty nursing (PDN) is defined as the provision of medically necessary, complex skilled nursing care in the home on a fee-for-service basis by a registered nurse (RN) or a licensed practical nurse (LPN). This service originated in the late 19th century and early 20th century as a direct result of the development of graduate nursing programs with limited employee opportunities. Though initially performed independent of MD direction/supervision, it has evolved to be an expanded form of home care under medical supervision. The purpose of PDN is to assess, monitor, and provide skilled nursing care in the home on an hourly basis; to assist in the transition of care from a more acute setting to home; and to teach competent caregivers the assumption of this care when the condition of the individual is stabilized. The purpose of private duty nursing is to provide skilled constant attention and observation to a seriously ill recipient. The need for, and the length of service, usually depends upon the condition of the recipient and the level of care required rather than the nature of the disease, illness, or condition. The length and duration of PDN is usually temporary in nature and not intended to be provided on a permanent ongoing basis.

Billing/Coding Information

CPT CODES

No specific codes identified

HCPCS CODES

S9123	Nursing care, in the home; by registered nurse, per hour
S9124	Nursing care, in the home; by licensed practical nurse, per hour
T1000	Private duty/independent nursing service(s), licensed, up to 15 minutes

Key References

1. Foster, C.C., et al. Connecting Hospital to Home: Characteristics of and Rehospitalization Rates in Hospitalized Children With Private-Duty Nursing. *Hosp Pediatr*. 2019 Jul;9(7):530-537. doi: 10.1542/hpeds.2018-0282. Epub 2019 Jun 12. PMID: 31189643.
2. Hayes, Inc. Clinical Research Response. GammaTile (GT Medical Technologies Inc.) for Brain Tumors. Jun 16, 2 Jean C. Whelan, PhD, RN When the Business of Nursing Was the Nursing Business The Private Duty Registry System, 1900-1940. Online J Issues Nurs. 2012;17(2).
3. Keepnews, D. (2011). Mapping the Economic Value of Nursing: A White Paper, Seattle: Washington State Nurses Association.
3. Oberwaldner, B. & Eber, E. 2016. Tracheostomy care in the home. *Paediatric Respiratory Reviews*, 7*(3)*, 185−190.
4. Roemer, NR. The tracheotomized child. Private duty nursing at home. *Home Healthcare Nurse*, 01 Jul 1992, 10*(4)*:28-32. doi: 10.1097/00004045-199207000-00006 PMID: 1644583023.

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Private Duty Nursing, continued

Revision History

Revision Date	Summary of Changes
10/3/24	For Commercial Plan Policy, modified criterion #3 as follows: "The member meets InterQual guidelines for SNF;"