
EXHIBIT ___
COORDINATING PROVISIONS-STATE/FEDERAL LAW, ACCREDITATION STANDARDS AND
GEOGRAPHIC EXCEPTIONS
MARYLAND

I. INTRODUCTION:

Scope. To the extent of any conflict between the Agreement and this State Law Coordinating Provisions (“SLCP”) Exhibit, this SLCP Exhibit shall supersede, govern and control to the extent required by federal and/or state law and to the extent that MPI, Network Provider and/or Client are subject to such federal or state law.

II. DEFINITIONS:

1. Depending upon the specific form of the Agreement, the following terms may be utilized in the Agreement and are intended to be defined as provided for in the Agreement:
 - (i) Billed Charges may be referred to as Regular Billing Rates;
 - (ii) Client may be referred to as Payor;
 - (iii) Contract Rates may be referred to as Preferred Payment Rates;
 - (iv) Covered Services may be referred to as Covered Care;
 - (v) Network Provider may be referred to as Preferred Provider;
 - (vi) Participant may be referred to as Covered Individual; and
 - (vii) Program or Benefit Program may be referred to as Contract.
2. For purposes of this Exhibit, the term Network Provider is inclusive of Participating Professional and all Network Providers.

III. FEDERAL LAW COORDINATING PROVISIONS:

Federal Employees Health Benefits (“FEHB”). As applicable, this Agreement is subject to the terms of the laws governing FEHB.

1. Federal Employees Health Benefits (“FEHB”) Plan. The parties agree that any and all claims or disputes relating to such benefits under a FEHB Plan will be governed exclusively by the terms of such federal government contract and federal law, whether or not such terms and laws are specified in this SLCP Exhibit or elsewhere in this Agreement.

IV. STATE LAW COORDINATING PROVISIONS: MARYLAND

For any Agreement involving the delivery of health care services in the State of Maryland, the provisions noted below shall apply. Where the term Client is used Client shall mean only those Clients that are subject to the specific law(s) cited below:

1. As required by Md. Code Ann., Ins. §15-123:

Experimental: refers to a procedure, device or therapy that has not been tested in humans, may or may not have been tested in animals, and in which the indications for usage, efficacy, and side effects remain unknown or highly controversial.

Investigational: refers to a procedure, device or therapy that is undergoing human trials. There are several levels of phases through which drug trials must pass:

1. Initial human trials on small numbers of individuals to establish acceptance by the human body.
2. Secondary human trials on small numbers of individuals to establish the Therapeutic Index; i.e., an acceptable dosage, route of administration, and level of side effects relative to efficacy.
3. Broad human trials involving thousands of patients, to ensure widespread acceptability and to refine indications, dosages, and intolerances.
4. General acceptance of the treatment, but not yet full FDA approval (e.g., use of methotrexate in treatment of rheumatoid arthritis: generally used and recognized as efficacious for the past ten years, but only approved in the last 5 years).

The following Clients have adopted the above definition:

Best Health Plans, LLC
Ecom Benefits, LLC
GMMI, Inc.
IHC Health Solutions, Inc.
Star Marketing and Administration, Inc. (A wholly owned subsidiary of Trustmark Insurance Company)
WebTPA.com, Inc.

CELTIC INSURANCE COMPANY

Experimental /Investigational is treatment or medication which includes, but is not limited to, a drug or procedure that is:

1. Administered pursuant to a consent document which describes the drug, device or procedure as being a part of a research project that is experimental or investigational;
2. Subject to the scrutiny of an Institutional Review Board, Peer Review Board or other body responsible for supervising biomedical research; and
3. Has among its objectives the determination of the following: toxicity, maximum tolerance dosage, effectiveness and effectiveness in comparison to alternative treatment.

A treatment or procedure is NOT considered to be experimental or investigational if it is all of the following:

1. Commonly performed on a widespread basis for treatment of the condition at issue;
2. Generally accepted by the medical profession as the standard and most effective form of treatment;
3. Proven safe and effective;
4. Medically necessary for the Participant;
5. Recognized for reimbursement as a covered procedure or treatment by Medicare, Medicaid and other insurers;
6. Used after other more conventional methods have been exhausted;
7. Not deemed experimental, investigational or under investigation by the FDA and/or the AMA; and
8. Legally obtainable.

CONNECTICARE

EXPERIMENTAL OR INVESTIGATIONAL

A service, supply or drug will, in our sole discretion, be considered Experimental or Investigational if any of the following conditions are present:

1. The service, supply or drug does not have final approval by the appropriate governmental regulatory body or bodies, or such approval for marketing has not been given at the time the service, supply or drug is furnished.
2. The prescribed service, supply or drug is available to you or your covered dependents only through participation in a program designated as a clinical trial, or an FDA Phase III experimental research clinical trial or a corresponding trial sponsored by the National Cancer Institute, or another type of clinical trial.
3. The protocols or consent documents of the entity prescribing or rendering the service, supply or drug describe the service, supply or drug as experimental or investigational.
4. A written informed consent form disclosing the experimental or investigational nature of the treatment for the specific service, supply or drug being studied has been reviewed and/or has been approved or is required by the treating facility's Institutional Review Board, or other body serving a similar function or if federal law requires such review and approval.
5. Authoritative medical or scientific literature published in the United States and written by experts in the field demonstrates that recognized medical or scientific experts:
 - Classify the service, supply or drug as experimental or investigational, or
 - Indicate that additional research is necessary before the service, supply or drug could be classified as equally or more effective than the conventional therapies.
6. As a whole the service, supply or drug would not be classified as Experimental or Investigational given the above criteria, but on or more essential feature of the service, supply or drug are Experimental or Investigational based on the above criteria.

In making a determination as to whether a prescribed service, supply or drug is or should be classified as Experimental or Investigational, the specific and exclusive resources to be relied on by us will be limited to:

1. Relevant medical information regarding you and the prescribed service, supply or drug.

2. The consent document signed, or required to be signed, in order for the Member to receive the prescribed service, supply or drug.
3. Documentation used by the treating facility's Institutional Review Board, or other body serving in a similar function.
4. Opinions advanced by peer review entities with which we contract to conduct reviews.
5. Authoritative peer reviewed medical or scientific literature published in the United States regarding the prescribed service, supply or drug for treatment of a Member's diagnosis.

Autologous bone marrow transplants for the treatment of breast cancer and the off-label uses of prescription drugs for the treatment of HIV/AIDS and cancer as required by applicable law will not be considered "Experimental or Investigational" for the purpose of coverage under this Certificate.

DEAN HEALTH SYSTEMS, INC. (d/b/a Dean Health Plan), Premier Medical Insurance Network Provider, Inc., SSM Health Care of Wisconsin

EXPERIMENTAL OR INVESTIGATIONAL SERVICES, TREATMENTS, OR PROCEDURES:

Those services, treatments or procedures that are determined by the Managed Care Division (with input from the Utilization Management Committee or the Quality Improvement Committee, as part of our quality improvement structure) to meet, as of the date of treatment, one or more of the following criteria:

1. The services, treatments or procedures involving the administration of a drug or the use of a device that is not approved by the U.S. Food and Drug Administration for treatment of the medical condition or symptoms for which the drug is being administered or the device is being used; or
2. Reliable evidence shows that the services, treatments or procedures are subject to ongoing Phase I, II, or III clinical trials or are under study to determine their maximum tolerated dose, their toxicity, their safety, their efficacy or their efficacy as compared with a standard means of treatment or diagnosis; or
3. Reliable Evidence shows that the prevailing opinion among experts regarding the services, treatments or procedures is that further clinical trials are necessary to determine their maximum tolerated dose, their toxicity, their safety, their efficacy or their efficacy as compared with a standard means of treatment or diagnosis.

"Reliable Evidence" shall mean only published reports and articles in authoritative medical and scientific literature; the written protocols or protocols used by the treating facility or by another facility studying substantially the same services, treatments or procedures; or the written informed consents used by the treating facility or by another facility studying substantially the same services, treatments or procedures.

DESTINY HEALTH INSURANCE COMPANY

Experimental, Investigational, or Unproven Services means those services and supplies that are:

1. Not approved by the Food and Drug Administration ("FDA"), the American Medical Association or the appropriate medical specialty society; or
2. Not approved by the Center for Health Care Technology within the Agency for Health Care Policy and Research within the Department of Health and Human Services for organ transplantation; or
3. Not demonstrated through peer-reviewed medical and scientific literature to be safe and effective in treating or diagnosing the proposed condition or illness.

ECOM BENEFITS, LLC

"Charges incurred for services, supplies, devices, treatments, procedures, and/or drugs that have not been recognized as generally accepted medical treatments. *Our* determination will be based on, but not limited to, the approval of treatments from: the American Medical Association, the U.S. Food and Drug Administration, Administrative Procedures Act, and treatments that have not been demonstrated through sufficient peer-review medical literature to be safe and effective for the purposed use."

ASSURANT HEALTH

Experimental or Investigational Services

Services, supplies or treatment which, at the time the charges were *incurred*, were:

1. not proven to be of benefit for the diagnosis or treatment of the *illness* or *injury*;
2. not generally recognized by the medical community as safe, effective, or appropriate for the *illness* or *injury*;

3. in the research or investigational stage, provided or performed in a special setting for research purposes, or under a controlled environment or clinical protocol;
4. obsolete or ineffective and not used generally by the medical community for the diagnosis or treatment of the *illness* or *injury*.

Governmental approval is not sufficient to prove services, supplies, or treatments of proven benefit are appropriate or effective for the diagnosis or treatment of the *illness* or *injury*. Only we can make the determination as to whether charges are for experimental or investigational services, based on the following criteria:

1. For any drug prescribed for the treatment of HIV/AIDS or a type of cancer for which the drug has not been approved by the Food and Drug Administration (FDA), use of the drug will require that one or more of the following recognize the usage as appropriate medical treatment:
 - a. The American Medical Association Drug Evaluations;
 - b. The American Hospital Formulary Services Drug Information; or
 - c. The United States Pharmacopeia Drug Information.

As an alternative to such recognition, the usage of the drug will be recognized as appropriate if: (a) it is supported by the preponderance of evidence that exists in clinical studies that are reported in generally accepted peer-reviewed medical literature or review articles; and (b) the FDA has not determined the medical device, drug or biological product to be contraindicated for the specific *illness* or *injury* for which the device, drug or biological product has been prescribed; or (c) as recognized by commissioner under state law.

2. For any devices, biological product, or other drug, final approval must have been received to market it by the Food and Drug Administration (FDA) for the particular *illness* or *injury*. Any other approval granted as an interim step in the FDA regulatory process, (e.g. an Investigational Device Exemption or an Investigational New Drug Exemption), is not sufficient. Once FDA approval has been granted, use of the device, drug or biological product for another *illness* or *injury* will require that one or more of the following recognize the usage as appropriate medical treatment:
 - a. The American Medical Association Drug Evaluations;
 - b. The American Hospital Formulary Services Drug Information; or
 - c. The United States Pharmacopeia Drug Information.

As an alternative to such recognition, the usage of the device, drug or biological product will be recognized as appropriate if: (a) it is supported by the preponderance of the evidence that exists in clinical studies that are reported in generally accepted peer-reviewed medical literature or review articles; and (b) the FDA has not determined the medical device, drug or biological product to be contradicted for the specific *illness* or *injury* for which it has been prescribed.

3. For any other services, supplies or treatments, conclusive evidence from generally accepted peer-reviewed literature must exist that:
 - a. the services, supplies or treatments have a definite positive effect on health outcomes. Such evidence must include well-designed investigations that have been reproduced by nonaffiliated authoritative sources, with measurable results, backed up by the positive endorsements of national medical bodies or panels regarding scientific efficacy and rationale;
 - b. over time the services, supplies or treatments lead to improvement in health outcomes, i.e. the beneficial effects outweigh any harmful effects;
 - c. the services, supplies or treatments are at least as effective in improving health outcomes as established technology, or are usable in appropriate clinical contexts in which established technology is not employable; and
 - d. improvement in health outcomes as defined above, is possible in standard conditions of medical practice, outside clinical investigatory settings.

In determining the above, we will rely on recognized medical sources such as, but not limited to: the Office of Health Technology Assessment, Health Care Financing Administration (HCFA), National Institute of Health, Diagnostic and Therapeutic Technology Assessment (DATTA) Project of the American Medical Association, Food and Drug Administration (FDA), the American Board of Medical Specialties and other broadly accepted medical authorities.

TRUSTMARK INSURANCE COMPANY (CoreSource, Inc. and CoreStar, a division of CoreSource, Inc.)

Experimental/Investigational

A drug, device or medical treatment or procedure is “experimental” or “investigational”

1. If the drug or device cannot lawfully be marketed without approval of the U.S. Food and Drug Administration and approval for marketing has not been given at the time the drug or device is furnished; or
2. If Reliable Evidence shows that the drug, device or medical treatment or procedure is the subject of ongoing Phase I, II or III clinical trials or under study to determine its maximum tolerated dose, its toxicity, its safety, its efficacy, or its efficacy as compared with the standard means of treatment or diagnosis; or
3. If Reliable Evidence shows that the consensus of opinion among experts regarding the drug, device or medical treatment or procedure is that further studies or clinical trials are necessary to determine its maximum tolerated dose, its toxicity, its safety, its efficacy or its efficacy as compared with the standard means of treatment or diagnosis.

“Reliable Evidence” means only published reports and articles in authoritative medical and scientific literature; the written protocol or protocols used by the treating facility or the protocols of another facility studying substantially the same drug, device or medical treatment or procedure; or the written informed consent used by the treating facility or by another facility studying substantially the same drug, device or medical treatment or procedure.

2. As required by Md. Code Annotated, Insurance §15-1005, Network Provider will submit claims for payment within one hundred eighty (180) days of furnishing health care services. Network Provider will follow the claims submission procedures contained in the administrative handbook(s).
3. As required by Md. Code Ann., §15-1009, if Client authorizes or certifies the performance of Covered Service for a Participant by Network Provider, Client shall not rescind or modify the amount of reimbursement due pursuant to a retrospective review by Client and/or MPI which determines that such Covered Service is not medically necessary; provided, however, Client may modify or rescind the amount of reimbursement due the Network Provider if:
 - (i) The information submitted to Client regarding the Covered Service delivered to the Participant was fraudulent or intentionally misrepresentative;
 - (ii) Critical information requested by the Client and/or MPI regarding the Covered Service to be delivered to the Participant was omitted such that the Client’s and/or MPI’s determination would have been different had it known the critical information;
 - (iii) A planned course of treatment for the Participant that was approved by the Client was not substantially followed by the Network Provider; or
 - (iv) On the date the preauthorized health care service was delivered:
 - a. The Participant was not covered by the Client;
 - b. The Client maintained an automated eligibility verification system that was available to the Preferred Provider by telephone or via the internet; and
 - c. According to the verification system, the Participant was not covered by the Client.

Prospective modification by Client of the prior authorization for Covered Services pursuant to a concurrent review shall not be deemed to be retrospective review pursuant to this Section.

2. As required by Md. Code Ann., Ins. §15-136, Client shall comply with the applicable payment provisions under Md. Code Ann., Ins. §15-136.

V. ACCREDITATION STANDARDS COORDINATING PROVISIONS:

There are no Accreditation Standards Coordinating Provisions at this time.

VI. GEOGRAPHIC EXCEPTIONS COORDINATING PROVISIONS:

There are no Geographic Exceptions Coordinating Provisions at this time.