

- b. _____ The patient has a disabling condition or disease which renders the patient unable to engage in any substantial gainful activities by reason of any medically determinable physical or mental impairment which can be expected to result in death or which has lasted or can be expected to last for a continuous period of not less than 12 months; or who, in case of a child under the age of eighteen (18), suffers from any medically determinable physical or mental impairment of comparable severity.

10. AND for which (please check one):

- [] Standard health services or procedures have been ineffective or would be medically inappropriate.
- [] There does not exist a more beneficial standard health service or procedure covered by the patient's health plan.
- [] There exists a clinical trial that is open, that the patient is eligible to participate in, and into which the patient has been or will likely be accepted.

(Please note: the clinical trial must be a peer-reviewed study plan which has been:

- (1) reviewed and approved by a qualified institutional review board; and
- (2) approved by either of the National Institutes of Health (NIH), or an NIH cooperative group or an NIH center, or the Food and Drug Administration in the form of an investigational new drug exemption, or the Federal Department of Veterans Affairs, or a qualified nongovernmental research entity as identified in guidelines issued by individual NIH Institutes for center support grants, or an institutional review board of a facility which has multiple project assurances approved by the Office of Protection from Research Risks of the National Institutes of Health. The term "cooperative groups" means formal networks of facilities that collaborate on research projects and have established NIH-approved peer review programs operating within their groups and that include, but are not limited to, the National Cancer Institute (NCI) Clinical Cooperative Groups; the NCI Community Clinical Oncology Program; the AIDS Clinical Trial Groups; and the Community Programs for Clinical Research in AIDS.)

11. AND (select a or b):

- a. _____ I have recommended a health service or procedure or a pharmaceutical product that, based on the following two (2) documents from the available medical and scientific evidence, is likely to be more beneficial to the patient than any covered standard health service or procedure.

Citation #1 (Describe the medical and scientific evidence relied upon, as defined below, and include publication name, issue number, and date, if available.)

Attach a copy of the document

Citation #2 (Describe the medical and scientific evidence relied upon, as defined below, and include publication name, issue number, and date, if available.)

Attach a copy of the document.

(Please note: medical and scientific evidence means the following sources: (a) peer-reviewed scientific studies published in, or accepted for publication by, medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff; (b) peer-reviewed medical literature, including literature relating to therapies reviewed and approved by a qualified institutional review board; biomedical compendia; and other medical literature that meet the criteria of the National Institute of Health's National Library of Medicine for

indexing in Index Medicus, Excerpta Medicus, Medline, and MEDLARS database Health Services Technology Assessment Research; (c) peer-reviewed abstracts accepted for presentation at major medical association meetings; (d) peer-reviewed literature does not include publications or supplements to publications sponsored to a significant extent by a pharmaceutical manufacturing company or medical device manufacturer; (e) medical journals recognized by the Secretary of Health and Human Services, under section 1861 (t) (2) of the federal Social Security Act; (f) the following standard reference compendia: (i) the American Hospital Formulary Service – Drug Information; (ii) the American Medical Association Drug Evaluation; (iii) the American Dental Association Accepted Dental Therapeutics; and (iv) the United States Pharmacopeia- Drug Information; (g) findings, studies, or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes including the federal Agency for Healthcare Policy and Research, National Institutes of Health, National Cancer Institute, National Academy of Sciences, Healthcare Financing Administration, Congressional Office Technology Assessment, and any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health services.)

OR

- b. _____ I have recommended a clinical trial that is open, that the patient is eligible to participate in, and into which the patient has been or will likely be accepted.

V Attestation

I attest that the above information is true and correct. I understand that I may be subject to professional disciplinary action for making false statements.

Attending Physician's Name (please print clearly)

Signature

Date

This application should be faxed to the New York State Insurance Department at **1-800-332-2729**. If you have any questions, please contact the Insurance Department at **1-800-400-8882**.