Cohere Medical Policy - Positron Emission Tomography (PET)/PET-Computed Tomography (CT)

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Other Notices:

Guideline Information:

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Service: Positron Emission Tomography (PET), PET/Computed Tomography (CT)

Recommended Clinical Approach

Positron emission tomography (PET) is a non-invasive diagnostic imaging procedure used to evaluate the metabolic activity in tissues. This technology is particularly useful for assessing oncologic, cardiovascular diseases and neurological disorders. Before undergoing a PET scan, patients typically undergo a series of preliminary assessments, including history and physical examination, and often other imaging studies like MRI or CT scans, which guide the need for further metabolic imaging[57-58].

Oncologic positron emission tomography (PET) is considered advanced imaging and best utilized per institutional oncologic protocols and oncologic (e.g., National Comprehensive Cancer Network [NCCN]) and radiological society guidelines including the Society of Nuclear Medicine and Molecular Imaging (SNMMI), the European Association of Nuclear Medicine (EANM), and the American College of Radiology (ACR). The decision to perform oncologic PET is often made at institutional tumor board meetings after multidisciplinary oncology teams review the case. Teams may include oncologic surgeons, radiation oncologists, medical oncologists, pathologists, and radiologists.[1-3]

Medical Necessity Criteria

Indications

➔ **Positron emission tomography (PET) with or without concurrently acquired computed tomography (CT)(PET/CT) using**

fluorodeoxyglucose (FDG) is considered appropriate if **ANY** of the following is **TRUE**[1-3]:

- Initial diagnosis of **ANY** of the following strongly suspected primary cancer/tumor types:
  - Anal carcinoma, biopsy-proven, if initial CT scan is insufficient for complete diagnosis[5]; **OR**
  - Adrenal tumor with **ANY** of the following:
    - When conventional imaging and biochemical evaluation are highly suggestive of adrenocortical carcinoma; **OR**
    - Pheochromocytoma/paraganglioma when initial SSTR PET is negative[4]; **OR**
  - Bladder cancer (muscle-invasive) when prior imaging suggests disease beyond urinary tract[6]; **OR**
  - Brain metastases with unknown primary with **ALL** of the following[8]:
    - Initial CT of the abdomen/pelvis; **AND**
    - Initial brain MRI; **AND**
    - Initial CT of the chest; **OR**
  - Breast cancer with prior indeterminate imaging[1,9-12]; **OR**
  - Cervical cancer with prior indeterminate imaging (pelvic MRI is also indicated in addition to PET); **OR**[13-14]
  - Colorectal cancer with **ANY** of the following[15-17]:
    - When standard imaging (CT chest, abdomen, and pelvis) cannot be performed or is indeterminate; **OR**
    - Potentially surgically curable metastatic disease (abdominal MRI is indicated in addition to PET when there are known or suspected liver metastases); **OR**
    - When image-guided liver-directed therapies are being considered; **OR**

- Endometrial carcinoma with prior indeterminate imaging[18-19]; **OR**
- Esophageal cancer after initial workup with CT/MRI if there was no evidence of metastatic disease[20-21]; **OR**
- Gastric cancer after initial workup with CT/MRI if there was no evidence of metastatic disease[22]; **OR**
- Head and neck cancer (in addition to PET, neck CT (or MRI) alongside CT (or MRI) of the primary site of disease are indicated)[24-26]; **OR**
- Lung cancer, non-small cell (brain MRI is also indicated in addition to PET)[27,68]; **OR**
- Lung cancer, small cell[28-29]; **OR**
- Lymphoma (depending on the subtype, neck CT, chest CT, brain MRI, and abdomen/pelvis CT may also be indicated in addition to PET)[30-31]; **OR**
- Biopsy-confirmed melanoma with **ANY** of the following[32]:
    - Positive sentinel node; **OR**
    - Standard imaging (CT chest, abdomen, pelvis) cannot be performed or is indeterminate for metastatic disease; **OR**
    - When the primary site is unknown and standard imaging is negative; **OR**
    - For surgical planning purposes; **OR**
    - Prior to initiation of systemic therapy; **OR**
    - Uveal melanoma[69]; **OR**
    - Mucosal melanoma; **OR**
- Multiple myeloma[33]; **OR**
- Smoldering myeloma[33]; **OR**
- POEMS Syndrome[33]; **OR**
- Epithelial ovarian cancer/fallopian tube cancer/primary peritoneal cancer with **ANY** of the following[34-36]:

    - With prior indeterminate imaging; **OR**
    - To direct the management of indeterminate lesions found on other imaging; **OR**
- Pancreatic cancer with **ANY** of the following[37-38]:
    - With prior indeterminate imaging; **OR**
    - When surgical resection is being considered; **OR**
    - With **ANY** of the following high-risk features:
        - Borderline resectable disease; **OR**
        - Markedly elevated CA19-9 (>180 U/ml); **OR**
        - Largely primary tumor/lymph nodes; **OR**
        - Patient is symptomatic (i.e., jaundice, gastric outlet obstruction, venous thromboembolism, extreme pain, excessive weight loss); **OR**
- Peritoneal mesothelioma, if suspected based on recurrent ascites or peritoneal thickening/mass[66]; **OR**
- Pleural mesothelioma (chest CT is indicated in addition to PET)[39]; **OR**
- Squamous cell skin carcinoma when the lymph node or metastatic site has been biopsied and shows disease spread[45]; **OR**
- Ewing sarcoma (chest CT and CT/MRI of the primary site are also indicated in addition to PET)[7]; **OR**
- Osteosarcoma (chest CT and CT/MRI of the primary site are also indicated in addition to PET)[7]; **OR**
- Soft tissue sarcoma with prior indeterminate imaging (chest CT and CT/MRI of the primary site are also indicated in addition to PET)[46]; **OR**
- Vulvar cancer (note: for vulvovaginal melanoma, see melanoma indication above) with **ANY** of the following[52]:
    - Prior indeterminate imaging; **OR**
    - Tumor extends beyond vulva/perineum; **OR**

        - Positive sentinel nodes; **OR**
        - Locally advanced disease (i.e. - unresectable without removing proximal urethra/bladder/anus); **OR**
        - Unresectable nodes; **OR**
    - Leukemia with **ANY** of the following:
        - Acute lymphoblastic leukemia (ALL) if lymphomatous extramedullary disease is suspected[70]; **OR**
        - Acute myeloid leukemia (AML) if extramedullary disease is suspected[71]; **OR**
        - Chronic lymphocytic leukemia (CLL) in order to direct nodal biopsy if histologic transformation (Richter transformation) is suspected[72]; **OR**
        - Adult T-cell leukemia[31]; **OR**
    - Other unspecified primary cancer/tumor when PET is felt to be necessary to sufficiently diagnose disease (i.e., initial presentation with suspected metastasis); **OR**
- Response to treatment monitoring or re-staging of **ANY** of the following biopsy-proven primary cancer/tumor types:
    - Adrenal[4]; **OR**
    - Anal[5]; **OR**
    - Bladder[6]; **OR**
    - Bone[7]; **OR**
    - Brain/central nervous system[8]; **OR**
    - Breast (including evaluation of response to hormonal therapy)[1,9-12]; **OR**
    - Cervical[13-14]; **OR**
    - Colorectal[15-17]; **OR**
    - Endometrial[18-19]; **OR**
    - Esophageal[20-21]; **OR**
    - Gastric[22]; **OR**
    - Gestational trophoblastic neoplasia[23]; **OR**

- Head and neck[24-26]; **OR**
- Leukemia with lymphomatous extramedullary disease[70,71]; **OR**
- Lung cancer, non-small cell[27]; **OR**
- Lung cancer, small cell[28-29]; **OR**
- Lymphoma[30-31]; **OR**
- Melanoma, cutaneous[32]; **OR**
- Multiple myeloma[33]; **OR**
- Ovarian[34-36]; **OR**
- Pancreatic[37-38]; **OR**
- Pleural mesothelioma[39]; **OR**
- Prostate (including evaluation of response to hormonal therapy)[40-44]; **OR**
- Squamous cell carcinoma of the skin[45]; **OR**
- Soft tissue sarcoma[46-47]; **OR**
- Testes[48-49]; **OR**
- Thyroid[50-51]; **OR**
- Vulvar[52]; **OR**

- Surveillance by **FDG-PET** or **PET/CT** (defined as monitoring after completion of treatment [radiotherapy, chemotherapy, surgery, etc.] as appropriate) is indicated for **ANY** of the following:
  - Adrenal tumor (pheochromocytoma/paraganglioma) with **ALL** of the following[4]:
    - Either locally unresectable disease or distant metastases; **AND**
    - **ANY** of the following:
      - Bone-dominant disease; **OR**
      - Prior SSTR-positive disease on SSTR-PET/CT; **OR**
      - When considering radionuclide therapy; **OR**
  - Bladder carcinoma that is known or suspected to be metastatic[6]; **OR**

- Ewing sarcoma[7]; **OR**
- Osteosarcoma[7]; **OR**
- Adult glioma or meningioma that is recurrent or progressive[8]; **OR**
- Breast cancer that is known or suspected to be metastatic[9]; **OR**
- Cervical cancer that is stage III or higher in the first 2 years following treatment[13]; **OR**
- Colorectal cancer with **ANY** of the following[15,16]:
    - Stage IV colon or rectal cancer before or after image-guided liver-directed therapies for liver metastases (i.e., thermal ablation, radioembolization); **OR**
    - Stage IV colon or rectal cancer with serial CEA elevation during follow-up; **OR**
- Endometrial cancer with suspected recurrence or metastasis based on clinical symptoms, physical findings, or abnormal laboratory results[18]; **OR**
- Esophageal cancer with **ANY** of the following[20]:
    - Single assessment of response to chemoradiation when performed at least 5 weeks after completion of therapy; **OR**
    - Among patients who cannot undergo traditional CT scan, PET/CT is appropriate every 6 months for up to 2 years, and then annually for up to 5 years; **OR**
- Gastric cancer patients who cannot undergo traditional CT scan[22]; **OR**
- Gestational trophoblastic neoplasia upon completion of treatment, and then every 6-12 months for 3 years[23]; **OR**
- Head and neck cancer if the end-of-therapy PET demonstrates possible residual disease, one additional PET

is appropriate at least 6 weeks after end-of-therapy PET as it may help identify those patients who can be safely observed without additional treatment[24]; **OR**

- Leukemia with lymphomatous extramedullary disease[70,71]; **OR**
- Lung cancer (non-small cell) after definitive treatment and **ANY** of the following[27]:
    - Known or suspected recurrence; **OR**
    - CT scan with indeterminate findings,; **OR**
- Lung cancer (small cell) only if contrast CT or MRI is contraindicated[28]; **OR**
- T-cell/Non-Hodgkin lymphoma for **ANY** of the following:
    - Prior indeterminate imaging requiring shorter interval follow-up (i.e., every 3 months); **OR**
    - No more than every 6 months for 2 years, and then annually for 5 years or as clinically indicated[31]; **OR**
- Melanoma, cutaneous, for **ANY** of the following[32]:
    - Primary disease in the extremities; **OR**
    - When previous disease was only able to be seen on PET: every 3 to 12 months for 2 years, and then every 6 to 12 months for another 3 years; **OR**
- Multiple myeloma surveillance on an annual basis, indefinitely[33]; **OR**
- Ovarian cancer for **ANY** of the following[34]:
    - When tumor markers are considered unreliable; **OR**
    - The physical exam is unreliable; **OR**
    - There is a high risk of recurrence; **OR**
    - Malignant sex cord-stromal tumors when patients have symptoms, elevated biomarkers, or suspicious findings on physical exam; **OR**
- Pancreatic cancer for with **ALL** of the following:

- Prior formal pancreatic CT protocol; **AND**
- High-risk feature, including but not limited to: equivocal or indeterminate imaging findings, markedly elevated CA 19-9, large primary tumors, or large regional lymph nodes[37]; **OR**

- Pleural mesothelioma[63-65]; **OR**
- Squamous cell carcinoma of the skin that is regional or S-ITM (satellite/in-transit metastasis [i.e., growing more than 2 centimeters away from primary tumor site]) if there is a risk of subclinical (i.e., not readily observable) recurrence[45]; **OR**
- Soft tissue sarcoma[46]; **OR**
- Testicular cancer (seminoma) for **ANY** of the following[48]:
  - Bulky clinical stage IIB, IIC, or stage III may be imaged every 4 months for the first year, every 6 months for the second year, annually for years 3 and 4, and as clinically indicated for years 5 and beyond; **OR**
  - Any recurrent seminoma as clinically indicated; **OR**
- Thyroid cancer with **ANY** of the following[50]:
  - Medullary carcinoma that is 2-3 months postop if calcitonin rises significantly (i.e., greater than 150 pg/mL), or if CEA is elevated; **OR**
  - Anaplastic carcinoma that is 3-6 months after completion of initial therapy; **OR**
- Vulvar cancer that is 3-6 months after definitive treatment[52]; **OR**
- Vulvar or vulvovaginal melanoma every 4-12 months[52]; **OR**
- Other evaluation of a new clinical sign or symptom that is concerning for progression, recurrence, or metastasis; **OR**

◆ Characterization of solitary pulmonary nodules (SPNs) as seen on low-dose CT or chest CT with **ANY** of the following:

- Greater than 8 millimeters in diameter (solid); **OR**
- Greater than 6 millimeters for part-solid nodules[62]; **OR**

◆ **F-18 fluciclovine, choline C-11, or prostate-specific membrane antigen (PSMA [using F-18 piflufolastat, F-18 flotufolastat, or Ga-68 PSMA-11]) PET** and the patient has prostate cancer/tumor and **ANY** of the following[40-44]:

- Diagnosis of prostate cancer (except fluciclovine) with equivocal results on initial bone scan and **ANY** of the following[40-44]:
  - Regional or metastatic disease; **OR**
  - Clinically localized disease that is unfavorable, intermediate, or high-risk with equivocal or indeterminate conventional imaging (i.e., bone scan, CT abdomen and/or pelvis, MRI pelvis, prostate MRI); **OR**
- Prostate cancer after prostatectomy with **ANY** of the following[40]:
  - PSA (prostate-specific antigen) does not fall to undetectable levels; **OR**
  - Undetectable PSA after radical prostatectomy with a subsequent detectable PSA that increases on at least 2 subsequent determinations; **OR**
  - To monitor known or suspected metastatic prostate cancer; **OR**
  - An increasing PSA or positive rectal exam after radiation therapy if the patient is a candidate for additional local therapy or systemic therapy; **OR**
  - Surveillance of new lesions (this includes additional confirmatory imaging after 8-12 weeks) with **ALL** of the following:
    - ◆ Falling PSA or soft tissue response; **AND**

        - The absence of pain progression ; **OR**
    - The patient has been treated with radiation therapy and **ANY** of the following:
        - An increase of PSA by 2 ng/mL or greater above the lowest post-treatment PSA; **OR**
        - PSA increasing after radiation therapy and the patient is a candidate for salvage local therapy (even if the lowest PSA value is under 2 ng/mL); **OR**
    - Initial treatment planning for suspected metastatic disease; **OR**
    - Staging for individuals with a diagnosis of unfavorable intermediate-risk, high-risk, or very high-risk prostate cancer; **OR**
    - GA-68 PSMA-11 PET/CT before initial treatment with lutetium Lu 177 vipivotide tetraxetan for metastatic castration-resistant prostate cancer; **OR**
- **Dotatate PET** for **ANY** of the following:
    - Meningioma when prior MRI or CT is indeterminate[78-81]; **OR**
    - The patient has a well-differentiated neuroendocrine tumor and **ANY** of the following[4,53];
        - Diagnosis; **OR**
        - Staging; **OR**
        - Restaging; **OR**
        - Treatment planning for 177-lutetium Lu Dotatate; **OR**
- **Positron emission tomography (PET) scan for non-oncologic conditions** is considered appropriate if **ALL** of the following are **TRUE**[59-60]:
    - MRI or CT are contraindicated or inconclusive**; AND**
    - **ANY** of the following is **TRUE**:

- For suspected musculoskeletal osteomyelitis, when MRI cannot be performed and CT is nondiagnostic; **OR**
- Biopsy-proven Castleman Disease[67]; **OR**
- Fever of unknown origin (FUO) after clinical (including labs and blood cultures) and other advanced imaging workup (CT or MR) are negative; **OR**
- Sarcoid when conventional testing (i.e., CT and inflammatory serology) are inconclusive to evaluate **ANY** of the following[82-84]:
  - Extent of disease; **OR**
  - Response to treatment, provided that the results will affect a change in management; **OR**
  - If sarcoid is suspected and there is a need for PET/CT to determine the most suitable site to biopsy; **OR**
- Known or suspected systemic vasculitis (e.g., aortitis, giant cell arteritis, Takayasu arteritis).[73-77]

Non-Indications

➔ **Positron emission tomography (PET), with or without concurrently acquired computed tomography (CT)(PET/CT)** is not considered appropriate if **ANY** of the following is **TRUE**:

- The patient has undergone advanced imaging of the same body part within 3 months without undergoing treatment or developing new or worsening symptoms[61]; **OR**
- **ANY** of the following:
  - Used as an initial screening test in asymptomatic individuals; **OR**
  - Whole-body PET or PET/CT for cancer screening purposes only; **OR**

- Initial diagnosis or staging of axillary lymph nodes in breast cancer[1,9-12]; **OR**
- Initial diagnosis of cervical cancer related to anti-tumor treatment strategy[1,13-14]; **OR**
- Initial staging of regional lymph nodes in melanoma[1,32]; **OR**
- Non-seminoma tumors of the testes[48-49]; **OR**
- Surveillance after definitive treatment of anal carcinoma[5]; **OR**
- Surveillance after definitive treatment of Hodgkin lymphoma[30]; **OR**
- Active surveillance of very-low risk prostate cancer (i.e., actively monitoring the course of disease with the expectation to intervene with curative intent if the cancer progresses)[40]; **OR**
- FDG-PET for the staging of prostate cancer.[40-44]

*NOTE: PET/CT in patients with claustrophobia should be requested at the discretion of the ordering provider.
**NOTE: PET/CT in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.[54]
***NOTE: PET scans should be scheduled at least 4–6 weeks after radiation therapy or surgery to avoid false positives due to inflammation from recent treatments.

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and

the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.[55-56]

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.[55-56]

Cumulative Dose Monitoring: Implement systems to track cumulative radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation.[55-56]

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images.[55-56]

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
78811	Positron emission tomography (PET) imaging of chest
78812	Positron emission tomography (PET) imaging of skull base to midthigh
78813	Positron emission tomography (PET) imaging of whole body
78814	Positron emission tomography (PET) with concurrently acquired computed tomography (CT)
78815	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging of skull base to midthigh
78816	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) of whole body
79101	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; whole body
A9515	Choline c-11, diagnostic, per study dose up to 20 millicuries
A9552	Fluorodeoxyglucose f-18 fdg, diagnostic, per study dose, up to 45 millicuries
A9587	Gallium ga-68, dotatate, diagnostic, 0.1 millicurie

A9588	Fluciclovine f-18, diagnostic, 1 millicurie
A9593	Gallium ga-68 psma-11, diagnostic, (ucsf), 1 millicurie
A9594	Gallium ga-68 psma-11, diagnostic, (ucla), 1 millicurie
A9595	Piflufolastat f-18, diagnostic, 1 millicurie
A9596	Gallium ga-68 gozetotide, diagnostic, (illuccix), 1 millicurie
A9597	Positron emission tomography radiopharmaceutical, diagnostic, for tumor identification, not otherwise classified
A9607	Lutetium Lu 177 vipivotide tetraxetan, therapeutic, 1 millicurie
A9608	Flotufolastat f18, diagnostic, 1 millicurie
A9609	Fludeoxyglucose f18 up to 15 millicuries
A9800	Gallium Ga-68 gozetotide, diagnostic, (Locametz), 1 millicurie
G0219	PET imaging whole body; melanoma for non-covered indications
G0235	PET imaging, any site, not otherwise specified
G0252	PET imaging, full and partial-ring scanners only, for initial diagnosis of breast cancer and/or surgical planning for breast cancer (e.g., initial staging of axillary

	lymph nodes)

Medical Evidence

Jadvar et al. (2017) published Appropriate Use Criteria for the Society of Nuclear Medicine and Molecular Imaging (SNMMI), the European Association of Nuclear Medicine (EANM), the American Society of Clinical Oncology (ASCO), the American College of Nuclear Medicine (ACNM) the Society for Pediatric Radiology (SPR), and the Canadian Association of Nuclear Medicine (CANM). The group focused on meta-analyses and large individual studies comparing PET or PET/CT with other imaging modalities. It stated that the physician must prioritize which modality to begin with. PET/CT is said to have a strong role in restaging cancers and determining future patient management. Clinical studies cited to support the accuracy of PET/CT in detecting recurrent disease and assessing treatment response.[3]

The American College of Radiology (ACR) published the ACR-ACNM-SNMMI-SPR practice parameter for performing FDG-PET/CT in oncology in 2021. The indications presented in the document include use in the staging of malignancy, monitoring response to therapy, or restaging when the patient has relapsed. Additionally, this imaging modality may help localize the site of the primary tumor in the setting of metastatic disease, clarify indeterminate results, or localize occult disease when testing such as tumor markers indicates neoplastic disease. Finally, FDG-PET/CT may be used to plan treatment goals and to guide biopsy and radiation treatment planning.[2]

Published by the American College of Radiology in 2023, the ACR-ACNM-SNMMI practice parameter for performing Gallium-68 and Copper-64 Dotatate PET/CT imaging for neuroendocrine tumors (NETs). This imaging modality is appropriate for diagnosing, staging, restaging, and assessing treatment response in neuroendocrine tumors. Radiotracers such as those discussed in this practice parameter, which target cell membrane expression of somatostatin receptors (SSTRs), are useful in evaluating

well-differentiated NETs compared to anatomical imaging. Fused imaging with computed tomography (PET/CT) in hybrid PET scanners has shown a high level of accuracy in evaluating patients with known or suspected malignancy.[53]

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Clinical Guideline Revision History/Information

Original Date: April 29, 2022		
Review History		
Version 2	8/15/2024	Annual review and policy restructure.
Version 3	10/30/2024	Edited repeat imaging criteria language.
Version 4	11/21/2024	Added solitary pulmonary nodule verbiage/reference and biopsy-proven language to indications
Version 5	3/13/2025	• Separated and revised surveillance criteria into new standalone indication based on NCCN guidance. • Separated and revised initial diagnosis criteria into new standalone indication based on NCCN guidance. • Indication for non-oncologic conditions expanded (Castleman Disease, Sarcoid) • Substantial copyediting throughout majority of policy for ease of use and clarity in language. • Added references.