GENERAL OVERVIEW OF EFFECTIVENESS GUIDANCE DOCUMENTS

Background and Purpose

The Center for Medical Technology Policy (CMTP) supports the development of Effectiveness Guidance

development or other forms of conditional approval will be useful policy tools to facilitate additional studies of

products. This should support greater certainty in decision making throughout the clinical development process, including very early decisions with respect to the commitment of resources to pursue for further development and key decisions at each phase of the clinical development process.

By considering existing regulatory guidance in the EGD process, and including the relevant FDA regulatory experts throughout the course of developing EGD recommendations

Scope and Topic Selection

Each EGD focuses on a specific category of health care technologies and/or a specific clinical condition. Examples of EGDs being developed by CMTP include treatments for chronic wounds, treatments for atrial fibrillation, patient-reported outcomes in oncology drug trials, cardiac imaging for diagnosis of coronary disease, and molecular diagnostics for choice of therapy in oncology, among others. Methodological considerations for the design of clinical studies will often be specific to defined categories of technologies or clinical conditions and the scope of EGDs must therefore be sufficiently narrow to provide study design recommendations that are specific and actionable. Although retrospective studies may be informative for

with a request that the draft EGD be further distributed by those that receive it; 2) the document is posted on