

# Allopurinol and cardiovascular outcomes in patients with ischaemic heart disease (ALL-HEART)

## **Clinical Endpoint Committee Charter**

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#### 1. Introduction

The primary objective of the ALL-HEART (Allopurinol and cardiovascular outcomes in patients with ischaemic heart disease) study is to determine whether allopurinol improves cardiovascular outcomes in patients with ischaemic heart disease (IHD). The primary endpoint of the study is the composite of non-fatal myocardial infarction, stroke and cardiovascular death. Secondary outcomes include all-cause mortality, quality of life and cost-effectiveness of allopurinol. Pre-specified cardiovascular and death events (see section 3) will be classified independently by the Clinical Endpoint Committee (CEC) utilising a consistent and unbiased classification system via an endpoint adjudication web portal. The CEC will be blinded regarding any information relating to the randomisation group.

#### 1.1 ALL HEART Study Management and Oversight Arrangements

ALL HEART is sponsored by the University of Dundee and NHS Tayside Health Board ("the Co-Sponsors").

The Chief Investigator is Dr Isla Mackenzie, an employee of the University of Dundee and holding an honorary contract with NHS Tayside ("the CI").

#### 2 Composition and responsibilities of the CEC

#### 2.1 CEC members and responsibilities

The CEC consists of the following physicians specialising in cardiology and/or stroke :

CEC Member	Affiliation
Professor Jon Townend (Chairman)	University Hospital Birmingham NHS Foundation Trust
Dr Helen Routledge	Worcestershire Acute Hospitals NHS trust
Dr Jasper Trevelyan	Worcestershire Acute Hospitals NHS Trust
Dr. Sohail Q. Khan	University Hospital Birmingham NHS Foundation Trust
Dr Sagar Doshi	University Hospital Birmingham NHS Foundation Trust
Dr Don Sims	University Hospital Birmingham NHS Foundation Trust

In the event that a CEC member is unable to continue participation, the CEC chairman will recommend a replacement to the CI. The CEC Chairman will take account of the views of the CI but the CEC Chairman will have the final decision as to the replacement. CEC members may not participate in the study as principal or co-investigators, nor should they routinely participate in the medical care of a patient in the study, except in an emergency.

The CEC Chairman will

• Act as the primary liaison between the CEC and the CI

- Act the primary liaison between the CEC and the study team
- Act as the primary liaison between the CEC, and the CEC contact at the Robertson Centre for Biostatistics (RCB), University of Glasgow
- Be responsible for the overall conduct of the CEC
- Review other reported cardiovascular and non-cardiovascular events (i.e. those not appearing to constitute event types requiring CEC adjudication) to ensure that potential endpoint events that would require CEC adjudication have not been missed
- Communicating with the Robertson Centre for Biostatistics (RCB) and the study team to resolve any data queries
- Liaising with the CEC members to arrange CEC meetings as necessary
- Ensuring that final event classification decisions reached as a result of CEC meetings are entered promptly into the endpoint adjudication web portal

CEC members will be responsible for:

- Participating in training on the adjudication process and study-specific events and definitions
- Reviewing the relevant clinical data about a subject identified as having experienced a suspected event that requires adjudication
- Adjudicating pre-specified clinical events (see section 3) according to the definitions outlined in section 5 of this charter and any other supporting documents supplied to the CEC by the study team or the Co-Sponsors
- Timely submission of event adjudication decisions
- Communicating with the study team about needs when necessary.
- Attending scheduled CEC meetings or teleconferences throughout the study

#### 2.2 CEC coordination staff and responsibilities

The CEC coordinating staff will be responsible for coordinating the day- to- day operations of the CEC. This includes:

- (a) Study team
- Assisting in developing trial-specific adjudication documents and forms
- Reviewing event data for those reported cardiovascular and non-cardiovascular events that require adjudication by the CEC (see section 3) to ensure that the information provided is adequate/complete

(b) RCB contact

 Liaising with the CEC Chair and study team regarding the endpoint adjudication process

#### 3 Events to be reviewed

The primary end point of the ALL-HEART trial is improvement in cardiovascular outcomes. Therefore fatal and non-fatal endpoints will require adjudication.

#### 3.1 Deaths

The CEC will review all reported deaths and classify the cause of death according to the following schema:

• Non-cardiovascular

- A definite non-cardiovascular cause of death must be identified
- Cardiovascular (CV)
  - Death due to acute myocardial infarction
  - Death due to stroke
  - Sudden cardiac death
  - Death due to heart failure
  - Cardiovascular procedure-related death
  - Other cardiovascular death (e.g. pulmonary embolism, ruptured aortic aneurysm)
- Undetermined cause of death (i.e. cause of death unknown)

#### Note on the classification of haemorrhagic deaths

Deaths due to gastrointestinal haemorrhage (e.g. from a peptic ulcer) will be classified as non-cardiovascular deaths.

Deaths due to vascular disease leading to fatal haemorrhage (e.g. ruptured aortic aneurysm) will be classified as "other cardiovascular" deaths (see above).

Deaths due to vascular trauma leading to fatal haemorrhage (e.g. stabbing) will be categorized as death due to trauma (non-cardiovascular death).

Similarly, deaths due to other types of secondary haemorrhage will be ascribed to the primary aetiology (e.g warfarin overdose, coagulopathy, etc) (non-cardiovascular death).

#### 3.2 Non-fatal events

The CEC will review the following reported non-fatal cardiovascular events:

- Acute myocardial infarction/biomarker positive acute coronary syndrome (reported to have been a reason for hospitalisation or to have occurred *during* a hospitalisation)
- Hospitalisation for angina\*/other cardiac chest pain (e.g. troponin-negative)\* (whether the angina/chest pain event was reported to have been the primary, or a contributing, reason for hospitalisation)
- Stroke/ possible stroke \*\* (whether reported to have been hospitalised or nonhospitalised or to have occurred *during* a hospitalisation)
- Hospitalisation for heart failure (whether the heart failure event was reported to have been the primary, or a contributing, reason for hospitalisation)

*NB:* Coronary/cerebral revascularisation procedures done over the course of the study will not be adjudicated by the CEC.

\*Reported hospitalisation for angina/other cardiac chest pain events are secondary study endpoints and such events will be reviewed by the CEC to ensure that acute myocardial infarction/biomarker positive ACS events have not been missed.

\*\*Brief documentation (eg discharge summary or clinic letter) relating to likely or definite TIAs, which are not thought by the study team to be stroke events, will be reviewed by the CEC chair to ensure that stroke events have not been missed. The CEC will not attempt to validate a diagnosis of TIA because of the difficulties (including the transience of the symptoms and the lack of a definitive test) involved in doing this reliably. Thus, reported TIA events will just be classified as 'stroke' or 'not a stroke'. If

requested by the CEC chair, a stroke endpoint package will be prepared for any TIA events where there is doubt over whether or not a stroke has occurred.

*NB* All hospitalised TIA events that are identified (e.g. from hospitalisation codes or by study site investigators) will be collected by the Study team during the course of the study.

Other non-fatal cardiovascular events will not routinely be reviewed by the CEC. However, these events will be reviewed by the study team to ensure that potential endpoint events which would require adjudication by the CEC are not missed. If the study team identifies a potential endpoint event, further information will be requested, as required and, if necessary, the event will be allocated to the CEC for adjudication.

#### 4 Adjudication process

The CEC chair will be copied into the first 20 reported events for review. A stroke physian will be involved in the review of any possible stroke events. For the first 20 reported events requiring adjudication, the events will be reviewed at a CEC meeting or teleconference with all CEC members, and the CEC chair present. The purpose of this committee review will be to ensure that all committee members are aligned with regard to the application of the event definitions described in this charter.

#### 4.1 Identification and reporting of events

All deaths and hospitalisations occurring within Scotland will be retrieved regularly from the General Register Office (GRO) database and the Scottish Morbidity Record One (SMR1) database, respectively. Hospitalisations and deaths occurring in England will also be retrieved regularly from centralised electronic records.

Potential endpoints will be identified when specific ICD and OPCS codes are detected electronically, using software created by the RCB. Potential endpoints may also be identified from manual SAE reporting throughout the study.

Deaths and hospitalisations that occur outside the Scottish and English record-linkage framework will be identified by the study team. These events will be identified as potential endpoints if appropriate by the study team.

When potential endpoint events are identified, trained nurses will scrutinise primary and secondary care records as well as death certification data, where appropriate. The data reviewed will be summarised onto *event pages* that have been specially designed to ensure that the information required for adjudication is captured. Where possible, the data will be supplemented by scanned images of relevant supportive source documentation (see section 4.7). Supportive source documents will be scrutinised to both patient identity and randomised drug exposure before review by the CEC. The event data will be posted on the endpoint adjudication portal by the study team for review by the CEC members.

The study team will review the *event packet* containing the relevant data for a reported event and check it for completeness. If required data is missing or incomplete, the process outlined in section 4.4 will be followed.

#### 4.2 RCB and study team review

*Event packets* for those events that require review by the CEC (see sections 3.1 and 3.2) will be allocated on a regular basis to a pair of CEC cardiology members (which will not include the Chairman) (or a pair of CEC members including at least one stroke physian for stoke events) and the pair will receive electronic notification that they have events ready for adjudication. The pairs will be rotated automatically in a manner that ensures that events are distributed to the members on an even basis. A full tracking system and audit including details of the date of dispatch to the CEC members will be utilised.

Those reported events *not* requiring formal adjudication by the CEC eg clearly noncardiac chest pain admissions, will be screened by the study team to ensure that events have not been missed or wrongly identified. A summary of these events will be available for review by the CEC chair on request. If the CEC chair considers that a potential endpoint event may have been missed, further information will be requested as required by the study team and, if necessary, the event will be forwarded to the CEC for adjudication.

Coronary revascularisation events will not be formally adjudicated by the CEC. Documentation relating to coronary revascularisation events (eg CABG or angiogram reports or discharge letters) will be collated by the study team and reviewed in batches by the CEC chair to confirm that these events are valid.

#### 4.3 Phase 1 CEC review

Upon receipt of a batch of *event packets* containing the relevant event data for suspected events, the adjudicating pair of CEC physicians will review each one independently and will enter their adjudication decisions onto the web portal. This is the Phase 1 review. For each event where the two reviewers have agreed on a classification, the event is deemed classified.

If the classification decision of the two reviewers is not unanimous, the event will be referred to the CEC chair for decision. The CEC chair may either elect to classify the event or to bring the event to the CEC committee for discusion and a majority decision.

#### Insufficient information to classify an event

If, at any time, a CEC member decides that a classification verdict is not obtainable because of incomplete/insufficient data, the process outlined in section 4.4 will be followed.

#### 4.4 Incomplete event data

If, having reviewed the event data pertaining to an event, the CEC chair, or a CEC member deems that the information therein is insufficient for the purposes of event adjudication, an electronic request for further information will be made directly to the study team, via the study web portal. This will be done by the CEC chair/ CEC member who will detail the specific information required. If the requested information is obtained and is deemed sufficient for the purpose of adjudication, the new *event packet* (including the new, or updated, event data) will be distributed to the relevant pair of CEC

members. This will then be reviewed independently by the pair of CEC members following the procedure outlined in section 4.3.

Alternatively, if the CEC chair or CEC member deems that the further information obtained is insufficient for the purpose of adjudicating an event, a new request for further information will be generated using the process described above.

In instances where it is confirmed that efforts to obtain requested information have been unsuccessful (e.g. because the study team has indicated that the information is not available despite best efforts to obtain it), classification of the event will be proceed on the available information. Discussion at a CEC meeting or may be scheduled if the CEC chair feels this is necessary.

#### 4.5 Phase 2 CEC review

The full CEC will convene at intervals throughout the study. In general, it is expected that that these will be teleconference meetings, however, a face- to- face meeting may substitute.

The primary objective of CEC meetings is the "Phase 2 review" and classification of those events for which a final classification decision has not been achieved by the Phase 1 review process outlined above (section 4.3). Phase 2 review of an event constitutes the discussion and adjudication of the event by the CEC as a group. Events discussed by the CEC as a group will be adjudicated by the majority vote. The Chair will have the casting vote if necessary. It is expected that at least 4 members including the Chair will be present at a CEC meeting.

The final classification decision for events discussed by the CEC as a group will be entered onto the web portal by the CEC chair. If the CEC are unable to arrive at a classification verdict for an event because of incomplete or inadequate information and it is felt that such information may be obtainable (e.g. the study team has *not* indicated that the information required is *not* available), the Chairman will detail the precise information/documentation that is needed to achieve classification and the study team will request this data using the process described in section 4.4. The event will be tabled and placed on the agenda for review at a subsequent CEC meeting when either the further information requested has been provided or when confirmation has been received that efforts to obtain the information have been unsuccessful. With respect to a death event; if, despite discussion, the cause of death remains unclear (and the study team has indicated that further information is *not* available despite best efforts to obtain it), the classification category "undetermined cause of death" will be used (see section 5.3.3).

#### 4.6 Adjudication timelines

The CEC members will expect events to be allocated as they become available on the ALL-HEART web portal, and will make every effort to enter their classification decisions onto the web-portal within 2 to 4 weeks from the time that the event data is received, although this may vary slightly. The prompt review/adjudication of events will be dependent on the CEC receiving the required event data (see 4.7) in a timely fashion and on the study team dealing with data-queries as promptly as possible.

For events requiring discussion at a CEC meeting, every effort will be made to ensure that such meetings take place in a timely fashion and that any final classification decisions reached are entered onto the web portal within 2 weeks of the meeting. If required, the above timelines may be amended as the study progresses, if the CEC and the other relevant parties agree.

#### 4.7 Clinical data to be provided

Event data for each potential endpoint event will be posted on a website portal by the study team and will include:

- a) A cover page that will identify the patient (by a unique patient identification number), and specify the event(s) to be adjudicated.
- b) The relevant completed *event page(s)* [each with a unique identifying event number] with the narrative (clinical summary) section(s).
- c) The appropriate supportive source documentation\* for each event

\*Where applicable and available, copies of the following source documentation should be provided for the following events:

#### Death event:

- Death certificate
- Autopsy report
- Relevant hospitalisation records (see "hospitalisation event", below)
- Discharge summary +/- clinical records or GP/paramedic records regarding the event

#### Hospitalisation event:

Relevant hospitalisation records, which may include:

- Hospital death/discharge summary
- Medical clerking records and relevant medical progress notes/continuation sheets (if required)
- Prescription charts (if required)

Potential myocardial infarction/biomarker positive ACS/angina/other chest pain event:

- ECGs: ECGs pertaining to the event and, if applicable, an ECG recorded before the event
- Cardiac enzyme/marker laboratory reports
- Other cardiovascular investigation reports as requested on the MI event page (e.g. exercise-ECG, echocardiography, myocardial perfusion scan)
- Cardiovascular operation/procedure reports (e.g coronary angiography)

Potential stroke/possible stroke event:

- Neuroimaging (CT brain, MRI brain, cerebral angiography) reports
- Key discharge or clinic letters
- Lumbar puncture report

Potential heart failure event

- ECGs: ECGs pertaining to the event and, if applicable, an ECG before the event
- Chest x-ray report
- Cardiac enzyme/marker laboratory report
- BNP/NT-proBNP report
- Other relevant cardiovascular investigation reports (e.g. echocardiography, radionuclide ventriculography)
- Cardiovascular operation/procedure reports

#### 5 Clinical Event definitions

#### 5.1 Hospitalisation

Hospitalisation is defined as an emergency/unplanned admission to a hospital setting (emergency room, observation or inpatient unit) that results in at least one overnight stay (i.e. a date change).

#### 5.2 Non-fatal events

#### Date of onset

For purposes of classification, when classifying events that are a cause of hospitalisation, the date of admission will be used as the onset date. In cases where the stated date of admission differs from the date the patient first presented to hospital with the event (e.g. because of a period of observation in an emergency department, medical assessment unit or equivalent), the date of initial presentation to hospital will be used (provided that the patient had not been discharged from hospital in the interim). For events where an admission date is not applicable (e.g. events occuring *during* an ongoing hospitalisation), the date of onset as reported by the treating physician will be used.

#### 5.2.1 Acute myocardial infarction

#### Note on biomarker elevations:

For cardiac biomarkers, laboratories should report an upper reference limit (URL). If the 99th percentile of the upper reference limit (URL) from the respective laboratory performing the assay is not available, then the URL for myocardial necrosis from the laboratory should be used. If the 99th percentile of the URL or the URL for myocardial necrosis is not available, the MI decision limit for the particular laboratory should be used as the URL.

#### Spontaneous acute myocardial infarction:

A rise and/or fall of cardiac biomarkers (troponin or CK-MB) should usually be detected (see note below) with at least one value above the upper reference limit (URL) together with evidence of myocardial ischemia with at least one of the following:

- Clinical presentation consistent with ischemia
- ECG evidence of acute myocardial ischaemia (as outlined in Table 1) or new left bundle branch block (LBBB)
- Development of pathological Q waves on the ECG (see Table 2)

- Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality
- Autopsy evidence of acute myocardial infarction

If biomarkers are elevated from a prior infarction, then a spontaneous myocardial infarction is defined as:

**a**. One of the following:

- Clinical presentation consistent with ischemia
- ECG evidence of acute myocardial ischemia (as outlined in Table 1) or new left bundle branch block. [The events committee will adjudicate in the context of the sequential ECG changes that are commonly seen in acute ST elevation/acute non-ST elevation myocardial infarction.]
- New pathological Q waves (see Table 2). [The events committee will adjudicate in the context of the sequential ECG changes that are commonly seen in acute ST elevation/acute non-ST elevation myocardial infarction.]
- Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality
- Autopsy evidence of acute myocardial infarction

#### <u>AND</u>

**b**. <u>Both of the following:</u>

- Evidence that cardiac biomarker values were decreasing (e.g. two samples 3-6 hours apart) prior to the suspected acute myocardial infarction\*
- ≥ 20% increase (and > URL) in troponin or CK-MB between a measurement made at the time of the initial presentation with the suspected recurrent myocardial infarction and a further sample taken 3-6 hours later

\*If biomarkers are increasing or peak is not reached, then a definite diagnosis of recurrent myocardial infarction is generally not possible.

#### Percutaneous coronary intervention-related acute myocardial infarction

Peri-percutaneous coronary intervention (PCI) acute myocardial infarction is defined by any of the following criteria. Symptoms of cardiac ischemia are not required.

- 1. Biomarker elevations within 48 hours of PCI:
  - Troponin or CK-MB (preferred) > 3 x URL <u>and</u>
  - No evidence that cardiac biomarkers were elevated prior to the procedure;

#### 

Both of the following must be true:

- $\geq$  50% increase in the cardiac biomarker result
- Evidence that cardiac biomarker values were decreasing (e.g. two samples 3-6 hours apart) prior to the suspected acute myocardial infarction
- 2. New pathological Q waves or new left bundle branch block (LBBB). [If the PCI was undertaken in the context of an acute myocardial infarction, the events committee will adjudicate in the context of the sequential ECG changes

that are commonly seen in acute ST elevation/acute non-ST elevation myocardial infarction.]

3. Autopsy evidence of acute myocardial infarction

#### Coronary artery bypass grafting-related acute myocardial infarction

Peri-coronary artery bypass graft surgery (CABG) acute myocardial infarction is defined by the following criteria. Symptoms of cardiac ischemia are not required.

- 1. Biomarker elevations within 72 hours of CABG:
  - Troponin or CK-MB (preferred) > 5 x URL <u>and</u>
  - No evidence that cardiac biomarkers were elevated prior to the procedure;

#### 

- Both of the following must be true:
  - $\geq$  50% increase in the cardiac biomarker result
  - Evidence that cardiac biomarker values were decreasing (e.g. two samples 3-6 hours apart) prior to the suspected acute myocardial infarction

#### <u>AND</u>

- 2. One of the following:
  - New pathological Q-waves (preferably with evidence of persistence)
  - New LBBB (preferably with evidence of persistence)
  - Angiographically documented new graft or native coronary artery occlusion
  - Imaging evidence of new loss of viable myocardium

#### 

3. Autopsy evidence of acute myocardial infarction

**Note:** For a diagnosis of acute myocardial infarction, elevation of cardiac biomarkers above the upper reference limit (or, if an URL is not available, above the local MI decision limit) should usually be present. If biomarkers are detectable but do not exceed the URL or the local MI decision limit, the classification "biomarker positive acute coronary syndrome" will be used, providing that the definition of this particular event-type (see below) is met.

However, myocardial infarction may be adjudicated for an event that has characteristics which are very suggestive of acute infarction but which does not meet the strict definition because biomarkers are not available (e.g. not measured) or are non-contributory (e.g. may have normalized).

Suggestive characteristics are:

 Typical cardiac ischemic-type pain/discomfort (except for suspected acute myocardial infarction occurring in the context of PCI or CABG where this requirement need not apply)

#### <u>AND</u>

- New ECG changes\* or other evidence to support a diagnosis of acute myocardial infarction (e.g. imaging evidence of new loss of viable myocardium/new regional all motion abnormality or angiography demonstrating occlusive coronary thrombus)
- \*If ECG tracings are not available for review, the CEC may adjudicate on the basis of reported ECG changes that have been clearly documented in the case records or in the case report form.

#### <u>Clinical classification of different types of myocardial infarction</u> Myocardial infarctions will be clinically classified as:

#### Type 1

Spontaneous myocardial infarction related to ischemia due to a primary coronary event such as plaque erosion and/or rupture, fissuring, or dissection.

#### Type 2

Myocardial infarction secondary to ischemia due to either increased oxygen demand or decreased supply, e.g. coronary artery spasm, coronary embolism, anaemia, arrhythmias, hypertension, or hypotension.

#### Type 3

Sudden unexpected cardiac death, including cardiac arrest, often with symptoms suggestive of myocardial ischemia, accompanied by presumably new ST elevation, or new LBBB, or evidence of fresh thrombus in a coronary artery by angiography and/or at autopsy, but death occurring before blood samples could be obtained, or at a time before the appearance of cardiac biomarkers in the blood.

#### Type 4a

Myocardial infarction associated with PCI.

#### Type 4b

Myocardial infarction associated with stent thrombosis as documented by angiography or at autopsy.

#### Type 5

Myocardial infarction associated with CABG.

Myocardial infarctions will be further sub-classified as:

1. ST segment elevation myocardial infarction (STEMI).

or

2. Non-ST segment elevation myocardial infarction (NSTEMI).

or

3. Myocardial infarction, type (i.e. STEMI or NSTEMI) unknown.

# Table 1: ECG manifestations of acute myocardial ischemia (in absenceof left ventricular hypertrophy and left bundle branch block)

#### **ST** elevation

New ST elevation at the J-point in two anatomically contiguous leads with the cut-off

points:  $\geq 0.2$  mV in men (> 0.25 mV in men < 40 years) or  $\geq 0.15$  mV in women in leads V2-V3 and/or  $\geq 0.1$  mV in other leads.

#### ST depression and T wave changes

New horizontal or down-sloping ST depression  $\ge 0.05$  mV in two contiguous leads; and/or new T wave inversion  $\ge 0.1$  mV in two contiguous leads.

The above ECG criteria illustrate patterns consistent with myocardial ischemia. In patients with abnormal biomarkers, it is recognized that lesser ECG abnormalities may represent an ischemic response and may be accepted under the category of abnormal ECG findings.

#### Table 2: Pathological Q waves:

- Any Q-wave in leads V2-V3 ≥ 0.02 seconds or QS complex in leads V2 and V3
- Q-wave ≥ 0.03 seconds and ≥ 0.1 mV deep or QS complex in leads I, II, aVL, aVF, or V4-V6 in any two leads of a contiguous lead grouping (I, aVL, V6; V4-V6; II, III, and aVF) a

A The same criteria are used for supplemental leads V7-V9, and for the Cabrera frontal plane lead grouping.

#### 5.2.2 Biomarker positive acute coronary syndrome (ACS)

**Note:** This does not include acute myocardial infarction which will be classified separately (see above).

For the diagnosis of biomarker positive ACS, the following criteria should be fulfilled: There should be:

1 Clinical presentation consistent with ischaemia (e.g. typical cardiac ischaemictype pain or discomfort).

#### and

2 Detectable cardiac biomarkers but without the fullfilment of the biomarker criteria outlined above for acute myocardial infarction.

[i.e. not exceeding the upper reference limit or, if an upper reference limit is not available, not exceeding the MI decision limit for the particular laboratory.]

#### and

3 The need for treatment with parenteral (intravenous, intra-arterial, buccal, transcutaneous or subcutaneous) anti-ischaemic/antithrombotic therapy and/or coronary revascularisation.

**Note:** The following are considered supportive of the diagnosis and, in general, at least one of these [(a), (b) or (c) ] is expected to be present. However, this is not mandatory

if the criteria 1 to 3 (above) are met and provided that the adjudicator is satisfied that the totality of the information is consistent with the diagnosis.

(a) New and/or reversible ST segment or T wave changes on the ECG.

(b) Investigations undertaken in view of the event (e.g. exercise ECG or stress myocardial perfusion scan) showing evidence of reversible myocardial ischaemia, (c) Coronary angiography showing angiographically significant coronary disease thought to be responsible for the patient's presentation. [If both invasive and CT angiographic imaging of the coronary arteries were performed, the results of the invasive coronary angiogram should take precedence.]

#### 5.2.3 Hospitalisation for troponin-negative cardiac chest pain\*

For the diagnosis of hospitalisation for troponin-negative cardiac chest pain, there should be emergency/unplanned admission to a hospital setting (emergency room, observation or inpatient unit) that results in at least one overnight stay (i.e. a date change) with fulfillment of the following criteria:

There should be:

1 Clinical presentation consistent with ischaemia (e.g. typical cardiac ischaemictype pain or discomfort) but without the fulfilment of the above diagnostic criteria for acute myocardial infarction or biomarker positive acute coronary syndrome.

#### and

2 The need for treatment with new or increased anti-anginal therapy (excluding sublingual nitrate therapy) and/or coronary revascularisation.

#### and

3 (a) New and/or reversible ST segment or T wave changes on the ECG. **Or** 

3 (b) Investigations undertaken in view of the event (e.g. exercise ECG or stress myocardial perfusion scan) showing evidence of reversible myocardial ischaemia. **Or** 

3 (c). Coronary angiography showing angiographically significant coronary disease thought to be responsible for the patient's presentation. [If both invasive and CT angiographic imaging of the coronary arteries were performed, the results of the invasive coronary angiogram should take precedence.]

#### and

4 The CEC should be satisified that angina was the primary reason for hospitalisation.

#### 5.2.4 Hospitalisation for other chest pain\* (not endpoint)

There should be:

- Emergency/unplanned admission to a hospital setting (emergency room, observation or inpatient unit) that results in at least one overnight stay i.e. a date change) due to chest pain but where the definitions (above) of acute myocardial infarction, biomarker positive ACS or angina are not met.
- The CEC or CEC chair should be satisfied that chest pain was the primary reason for

hospitalisation.

\*These events are not study endpoints but the definitions provided for these events will be used by the CEC or CEC chair to categorise reported myocardial infarction, biomarker positive ACS, angina and chest pain events that do not meet the study definitions of acute myocardial infarction or biomarker positive acute coronary syndrome.

#### 5.2.5 Stroke

Stroke is defined as an acute episode of neurological dysfunction caused by focal or global brain, spinal cord, or retinal vascular injury.

For the diagnosis of stroke, the following 4 criteria should usually be fulfilled:

- 1. Rapid onset\* of a focal/global neurological deficit with at least one of the following:
  - Change in level of consciousness
  - Hemiplegia
  - Hemiparesis
  - Numbress or sensory loss affecting one side of the body
  - Dysphasia/aphasia
  - Hemianopia (loss of half of the field of vision of one or both eyes)
  - Complete/partial loss of vision of one eye
  - Other new neurological sign(s)/symptom(s) consistent with stroke

\*If the mode of onset is uncertain, a diagnosis of stroke may be made provided that there is no plausible non-stroke cause for the clinical presentation.

#### 2. Duration of a focal/global neurological deficit > 24 hours

- or
- < 24 hours if (i) t
  - this is because of at least one of the following therapeutic interventions:
    - (a) pharmacologic i.e. thrombolytic drug administration.
    - (b) non-pharmacologic i.e. neurointerventional procedure (e.g. intracranial angioplasty).
  - or
  - (ii) brain imaging available clearly documenting a new haemorrhage or infarct.
  - or
  - (iii) the neurological deficit results in death.
- **3.** No other readily identifiable non-stroke cause for the clinical presentation (e.g. brain tumour, hypoglycaemia, peripheral lesion).

#### 4. Confirmation of the diagnosis by at least one of the following\*\*:

- a) Neurology, stroke or neurosurgical specialist.
- b) brain imaging procedure (at least one of the following):
  - (i) CT scan ( a normal CT scan does not rule out cerebral infarction).
  - (ii) MRI scan.
  - (iii) cerebral vessel angiography.

c) lumbar puncture (i.e. spinal fluid analysis diagnostic of intracranial haemorrhage).

\*\*If a stroke is reported but evidence of confirmation of the diagnosis by the methods outlined above is absent, the event will be discussed by the CEC members adjudicating the event with the CEC chair. In such cases, the event may be adjudicated as a stroke on the basis of the clinical presentation alone but only with agreement of the CEC chair.

Strokes will be further sub-classified as:

- Ischaemic (non-hemorrhagic) stroke (ie caused by an infarction of central nervous system tissue).
- or
- Hemorrhagic stroke (ie caused by nontraumatic intraparenchymal, intraventricular or subarachnoid hemorrhage).
- or
- Stroke type (i.e. hemorrhagic or ischaemic) unknown (i.e when imaging/other investigations are unavailable or inconclusive).

#### 5.2.6 Hospitalisation for heart failure

For the diagnosis of hospitalisation for heart failure, there should be emergency/unplanned admission to a hospital setting (emergency room, observation or inpatient unit) that results in at least one overnight stay (i.e. a date change) with fulfillment of the following criteria:

There should be:

- 1. clinical manifestations of new or worsening heart failure including at least one of the following:
  - New or worsening dysphoea on exertion
  - New or worsening dysphoea at rest
  - New or worsening fatigue/decreased exercise tolerance
  - New or worsening orthopnoea
  - New or worsening PND (paroxysmal nocturnal dyspnoea)
  - New or worsening lower limb or sacral oedema
  - New or worsening pulmonary crackles/crepitations
  - New or worsening elevation of JVP (jugular venous pressure)
  - New or worsening third heart sound or gallop rhythm

#### And

- 2. Investigative evidence of structural or functional heart disease (<u>if available</u>) with at least *one* of the following:
  - Radiological evidence of pulmonary edema/congestion or cardiomegaly.
  - Imaging (e.g. echocardiography, cardiac magnetic resonance imaging, radionuclide ventriculography) evidence of an abnormality (e.g. left ventricular systolic dysfunction, significant valvular heart disease, left ventricular hypertrophy).

- Elevation of BNP or NT-proBNP levels.
- Other investigative evidence of structural or functional heart disease (e.g evidence obtained from pulmonary artery catheterisation).

#### And

- 3. Need for new/increased therapy\* *specifically* <u>for the treatment of heart failure</u> including at least one of the following:
  - New or increased oral therapy for the treatment of heart failure
  - (See note on oral therapy, below).
  - Initiation of intravenous diuretic, inotrope, vasodilator or other recognised intravenous heart failure treatment or uptitration of such intravenous therapy if already receiving it.
  - Mechanical or surgical intervention (e.g. mechanical or non-invasive ventilation, mechanical circulatory support, heart transplantation, ventricular pacing to improve cardiac function), or the use of ultrafiltration, hemofiltration, dialysis or other mechanical or surgical intervention that is specifically directed at treatment of heart failure.

\*If time does not allow for the initiation of, or an increase in, treatment directed at heart failure or if the circumstances were such that doing so would have been inappropriate (e.g. patient refusal), the CEC will adjudicate on clinical presentation and, if available, investigative evidence.

Note on oral therapy: In general, for an event to qualify as *heart failure requiring hospitalisation* on the basis of *oral* heart failure therapy (i.e. in cases where none of the intravenous or non-pharmacological therapies listed above have been utilised), the new or increased oral therapy should include oral diuretics. However, in special cases, other new or increased oral therapy (e.g. hydralazine/long acting nitrate, aldosterone antagonist) may be accepted provided that the adjudication committee is satisfied that:

 a) the new or increased oral therapy was primarily directed at treating clinical manifestations of new or worsening heart failure (rather than, for example, initiation or uptitration of heart failure therapy as part of the routine optimisation of medical therapy).

and

b) the totality of the evidence indicates that heart failure, rather than any other disease process, was the primary cause of the clinical presentation.

#### And

4. The CEC should be satisfied that heart failure was the primary disease process accounting for the clinical presentation.

#### 5.3 Fatal events

In cases where a patient experiences an event and later dies due to that event, the event causing death and the death will be considered as separate events *only* if they are separated by a change in calendar day. If the event causing death and the death occur on the same calendar day, death will be the only event classified.

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#### 5.3.1 Cardiovascular deaths

**Cardiovascular death** includes death resulting from an acute myocardial infarction, sudden cardiac death, death due to heart failure, death due to stroke and death due to other cardiovascular causes as follows:

**Death due to Acute Myocardial Infarction** refers to a death usually occurring up to 30 days after a documented acute myocardial infarction (verified either by the diagnostic criteria outlined above for acute myocardial infarction or by autopsy findings showing recent myocardial infarction or recent coronary thrombus) due to the myocardial infarction or its immediate consequences (e.g. progressive heart failure) and where there is no conclusive evidence of another cause of death.

If death occurs before biochemical confirmation of myocardial necrosis can be obtained, adjudication should be based on clinical presentation and other (e.g. ECG, angiographic, autopsy) evidence.

NOTE: This category will include sudden cardiac death, involving cardiac arrest, often with symptoms suggestive of myocardial ischemia, and accompanied by presumably new ST elevation\*, or left new left bundle branch block\*, or evidence of fresh thrombus in a coronary artery by coronary angiography and/or at autopsy, but death occurring before blood samples could be obtained, or at a time before the appearance of cardiac biomarkers in the blood (i.e. acute myocardial infarction Type 3 – see section 5.2, above).

\*If ECG tracings are not available for review, the CEC may adjudicate on the basis of reported new ECG changes that have been clearly documented in the case records or in the case report form.

Death resulting from a procedure to treat an acute myocardial infarction [percutaneous coronary intervention (PCI), coronary artery bypass graft surgery (CABG)], or to treat a complication resulting from acute myocardial infarction, should also be considered death due to acute myocardial infarction.

Death resulting from a procedure to treat myocardial ischemia (angina) or death due to an acute myocardial infarction that occurs as a direct consequence of a cardiovascular investigation/procedure/operation that was not undertaken to treat an acute myocardial infarction or its complications should be considered as a death due to other cardiovascular causes.

**Sudden Cardiac Death** refers to a death that occurs unexpectedly in a previously stable patient. The cause of death should not be due to another adjudicated cause (e.g. acute myocardial infarction Type 3 – see section 5.2 above). The following deaths should be included.

a Dooth withoese of and instantaneous without new or wers

a. Death witnessed and instantaneous without new or worsening symptomsb. Death witnessed within 60 minutes of the onset of new or worsening symptoms unless a cause other than cardiac is obvious.

c. Death witnessed and attributed to an identified arrhythmia (e.g., captured on an ECG recording, witnessed on a monitor), or unwitnessed but found on implantable cardioverter-defibrillator review.

d. Death in patients resuscitated from cardiac arrest in the absence of pre-existing circulatory failure or other causes of death, including acute myocardial infarction, and who die (without identification of a non-cardiac aetiology) within 72 hours or without gaining consciousness; similar patients who died during an attempted resuscitation. e. Unwitnessed death without any other cause of death identified (information regarding the patient's clinical status in the 24 hours preceding death should be provided, if available)

Sudden cardiac death events will be further subclassifed by the CEC as:

- Sudden cardiac death due to a documented arrhythmia (i.e. arrhythmia adjudged to be the primary terminal event <u>and</u> documented evidence of the arrhythmia)
- 2) "Other" sudden cardiac death (i.e. not classifiable as being due to a documented arrhythmia)
   [e.g. insufficient evidence to suggest that an arrhythmia was the primary terminal event and/or no documented evidence of an arrhythmia]

**Death due to Heart Failure** refers to a death occurring in the context of clinically worsening symptoms and/or signs of heart failure without evidence of another cause of death (e.g. acute myocardial infarction).

Death due to heart failure should include sudden death occurring during an admission for worsening heart failure as well as death from progressive heart failure or cardiogenic shock following implantation of a mechanical assist device.

New or worsening signs and/or symptoms of heart failure include any of the following: **a**. New or increasing symptoms and/or signs of heart failure requiring the initiation of, or an increase in, treatment directed at heart failure or occurring in a patient already receiving maximal therapy for heart failure

Note: If time does not allow for the initiation of, or an increase in, treatment directed at heart failure or if the circumstances were such that doing so would have been inappropriate (e.g. patient refusal), the CEC will adjudicate on clinical presentation and, if available, investigative evidence.

**b**. Heart failure symptoms or signs requiring continuous intravenous therapy or chronic oxygen administration for hypoxia due to pulmonary edema.

c. Confinement to bed predominantly due to heart failure symptoms.

**d**. Pulmonary edema sufficient to cause tachypnea and distress <u>not</u> occurring in the context of an acute myocardial infarction, worsening renal function (that is not wholly explained by worsening heart failure/cardiac function) or as the consequence of an arrhythmia occurring in the absence of worsening heart failure.

**e**. Cardiogenic shock <u>**not**</u> occurring in the context of an acute myocardial infarction or as the consequence of an arrhythmia occurring in the absence of worsening heart failure

**Death due to Stroke** refers to death after a documented stroke (verified by the diagnostic criteria outlined above for stroke or by typical post mortem findings) that is either a direct consequence of the stroke or a complication of the stroke and where there is no conclusive evidence of another cause of death.

NOTE: In cases of early death where confirmation of the diagnosis cannot be obtained, the CEC may adjudicate based on clinical presentation alone.

Death due to a stroke reported to occur as a direct consequence of a cardiovascular investigation/procedure/operation will be classified as death due to other cardiovascular cause.

**Death due to Other Cardiovascular Causes** refers to a cardiovascular death not included in the above categories [e.g. pulmonary embolism, cardiovascular intervention (other than one performed to treat an acute myocardial infarction or a complication of an acute myocardial infarction – see definition of death due to myocardial infarction, above), aortic aneurysm rupture, or peripheral arterial disease]. Mortal complications of cardiac surgery or non-surgical revascularisation should be classified as cardiovascular deaths.

#### 5.3.2 Non-cardiovascular deaths

A non-cardiovascular death is defined as any death that is not thought to be due to a cardiovascular cause. There should be unequivocal and documented evidence of a non-cardiovascular cause of death.

Further subclassification of non-cardiovascular death will be as follows:

- Pulmonary
- Renal
- Gastrointestinal
- Infection (includes sepsis)
- Non-infectious (e.g., systemic inflammatory response syndrome (SIRS))
- Malignancy
- Hemorrhage, not intracranial
- Accidental/Trauma
- Suicide
- Non-cardiovascular surgery
- Other non-cardiovascular, specify

#### 5.3.3 Undetermined cause of death

This refers to any death not attributable to one of the above categories of cardiovascular death or to a non-cardiovascular cause (e.g. due to lack of information such as a case where the only information available is "patient died"). It is expected that every effort will be made to provide the adjudicating committee with enough information to attribute deaths to either a cardiovascular or non-cardiovascular cause so that the use of this category is kept to a minimal number of patients.

#### 6 Approvals

The following have approved this Charter:

#### **Signature**

Date

Professor Jon Townend (CEC Chair)

Dr Helen Routledge (CEC Member)

Dr Jasper Trevelyan (CEC Member)

Dr Sohail Q. Khan (CEC Member)

Dr Sagar Doshi (CEC Member)

Dr Don Sims (CEC Member)

Prof Ian Ford (Study statistician)

Dr Isla Mackenzie (Chief Investigator)

(Authorised Signatory for the Co-

Sponsors)

### Appendix A. ICD and OPCS CODES

Potential endpoints of interest to the CEC will be identified by searching electronically for the following codes:

CODE type	Code	Description
DISEASE CODES		
CHEST PAINS		
ICD10	R07.0	Pain in throat
ICD10	R07.1	Chest pain on breathing/painful respiration
ICD10	R07.2	Precordial pain
ICD10	R07.3	Other chest pain/anterior chest wall pain
ICD10	R07.4	Chest pain unspecified
CORONARY HEART DISEASE		
STABLE ANGINA		
ICD10	120	Angina pectoris
ICD10	125	Chronic ischaemic heart disease
ICD10	1250	Atherosclerotic cardiovascular disease, so described
ICD10	1251	Atherosclerotic heart disease
ICD10	1209	Angina pectoris, unspecified
ICD10	1201	Angina pectoris with documented spasm
ICD10	1258	Other forms of chronic ischaemic heart disease
ICD10	1259	Chronic ischaemic heart disease, unspecified
ICD10	1208	Other forms of angina pectoris
ACUTE CORONARY SYNDROMES		
ICD10	1200	Unstable angina
ICD10	121	Acute myocardial infarction
ICD10	1210	Acute transmural myocardial infarction of anterior wall
ICD10	1211	Acute transmural myocardial infarction of inferior wall
ICD10	1212	Acute transmural myocardial infarction of other sites
ICD10	1213	Acute transmural myocardial infarction of unspecified site
	1214	Acute subendocardial myocardial infarction
	1219	Acute myocardial infarction, unspecified
	122	Subsequent myocardial infarction
	1220	Subsequent myocardial infarction of antenor wall
	1221	Other forms of acute ischaomic boart disease
	1240	Acute ischaemic heart disease upspecified
	1243	Acute ischaemic heart disease, unspecified
	124	Coropary thrombosis not resulting in myocardial infarction
	1240	Subsequent myocardial infarction of other sites
ICD10	1220	Subsequent myocardial infarction of unspecified site
COMPLICATIONS OF ACUTE MYOC	ARDIAL INFARC	TION
		Certain current complication follow acute myocardial
ICD10	123	infarct
		Haemopericardium as curr comp folow acut myocard
ICD10	1230	infarct
ICD10	1231	Atral sept defect as curr comp folow acut myocardal infarct
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ICD10	1232	Ventric sep defect as curr comp fol acut myocardal infarc Rup cardac wal withou haemopercard as cur comp fol ac
ICD10	1233	MI Rup chordae tendinae as curr comp fol acut myocard
ICD10	1234	infarct Rup papilary muscle as curr comp fol acute myocard
ICD10	1235	infarct
ICD10	1236	MI
ICD10	1238	Oth current comp following acute myocardial infarction
ICD10	1241	Dressler's syndrome
ICD10	1253	Aneurysm of heart
ICD10	1510	Cardiac septal defect acquired
ICD10	1511	Rupture of chordae tendineae, not elsewhere classified
ICD10	1512	Rupture of papillary muscle, not elsewhere classified
ICD10	1512	Intracardiac thrombosis not elsewhere classified
PREVIOUS MYOCARDIAL INFARCTI		
	1252	Old myocardial infarction
OTHER CORONARY HEART DISEAS	SE	
ICD10	1254	Coronary artery aneurysm
ICD10	1256	Silent myocardial ischaemia
CEREBROVASCULAR DISEASES		
ICD10	160	Subarachnoid haemorrhage
		Subarachnoid haemorrhage from carotid siphon and
ICD10	1600	bifurcation
ICD10	1601	Subarachnoid haemorrhage from middle cerebral artery Subarachnoid haemorrhage from anterior communicating
ICD10	1602	artery Subarachnoid haemorrhage from posterior communicating
ICD10	1603	artery
ICD10	1604	Subarachnoid haemorrhage from basilar artery
ICD10	1605	Subarachnoid haemorrhage from vertebral artery Subarachnoid haemorrhage from other intracranial
ICD10	1606	arteries Subarachnoid haemorrhage from intracranial artery
ICD10	1607	UNSPEC
ICD10	1608	Other subarachnoid haemorrhage
ICD10	1609	Subarachnoid haemorrhage, unspecified
ICD10	161	Intracerebral haemorrhage
ICD10	1610	Intracerebral haemorrhage in hemisphere, subcortical
ICD10	1611	Intracerebral haemorrhage in hemisphere, cortical
ICD10	1612	Intracerebral haemorrhage in hemisphere, unspecified
ICD10	1613	Intracerebral haemorrhage in brain stem
ICD10	1614	Intracerebral haemorrhage in cerebellum
ICD10	1615	Intracerebral haemorrhage intraventricular
ICD10	1616	Intracerebral haemorrhage, multiple localized
	1618	Other intracerebral baemorrhage
	1610	Intracerebral haemorrhage unspecified
	162	Ather pontraumatic intracranial haemorrhage
	1620	Subdural baemorrhage (acute)(nontraumatic)
	1020	Nontraumatic extradural hapmorrhage
	1021	Intracranial bemorrhage (nontraumatic) unspecified
	1023	Corobral infarction
	103	

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ICD10	1630	Cerebral infarct due to thrombosis of precerebral arteries
ICD10	l631	Cerebral infarction due to embolism of precerebral arteries
ICD10	1632	Cereb infarct due unsp occlusion or stenos precerebrl arts
ICD10	1633	Cerebral infarction due to thrombosis of cerebral arteries
ICD10	1634	Cerebral infarction due to embolism of cerebral arteries
ICD10	1635	Cerebrl infarct due unspec occlusion or stenos cerebrl arts Cereb infarct due cerebral venous thrombosis.
ICD10	1636	nonpyogenic
ICD10	1638	Other cerebral infarction
ICD10	1639	Cerebral infarction, unspecified
ICD10	I64X	Stroke, not specified as haemorrhage or infarction
ICD10	165	Occlusion/stenos precerebral arts not result cerebrl infarct
ICD10	1650	Occlusion and stenosis of vertebral artery
ICD10	1651	Occlusion and stenosis of basilar artery
ICD10	1652	Occlusion and stenosis of carotid artery
ICD10	1653	Occlusion and stenosis of multip and bilat precerebrl arts
ICD10	1658	Occlusion and stenosis of other precerebral artery
ICD10	1659	Occlusion and stenosis of unspecified precerebral artery
ICD10	G45	Transient ischaemic attack/transient cerebral ischaemia
ICD10	166	Occlusion/stenosis cerebral arts not result cerebral infarct
ICD10	1660	Occlusion and stenosis of middle cerebral artery
ICD10	1661	Occlusion and stenosis of anterior cerebral artery
ICD10	1662	Occlusion and stenosis of posterior cerebral artery
ICD10	1663	Occlusion and stenosis of cerebellar arteries
	1664	Occlusion and stenosis of multiple and bilat cerebril arts
	1668	Occlusion and stenosis of other cerebral artery
	1669	Occlusion and stenosis of unspecified cerebral artery
	167	Other cerebrovascular diseases
	1670	Dissection of cerebral arteries popruptured
	1671	Cerebral aneurysm nonruptured
	1672	Cerebral atherosclerosis
	1673	Progressive vascular leukoencenhalonathy
	1674	Hypertensive encephalopathy
	1675	Movamova disease
	1676	Nonpyogenic thrombosis of intracranial venous system
	1677	Cerebral arteritis not elsewhere classified
	1678	Other specified cerebrovascular diseases
	1679	Cerebrovascular disease unspecified
		Cerebrovascular disorders in diseases classified
ICD10	168	elsewhere
ICD10	1680A	Cerebral amyloid angiopathy
ICD10	l681A	Cerebral arteritis in infect & parasit dis classif elsewh
ICD10	1682A	Cerebral arteritis in other diseases classified elsewhere
ICD10	1688A	Other cerebrovascular disorders in diseases EC
ICD10	169	Sequelae of cerebrovascular disease
ICD10	1690	Sequelae of subarachnoid haemorrhage
ICD10	1691	Sequelae of intracerebral haemorrhage
ICD10	1692	Sequelae of other nontraumatic intracranial haemorrhage
ICD10	1693	Sequelae of cerebral infarction
ICD10	1694	Sequelae of stroke, not spec as haemorrhade or infarction
		Sequelae of other and unspecified cerebrovascular
ICD10	1698	diseases
ICD10	170	Atherosclerosis
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		Transient cerebral ischaemic attacks and related
ICD10	G45	syndromes
ICD10	G450	Vertebro-basilar artery syndrome
	G451	Carotid artery syndrome (bemispheric)
	G451	Multiple and bilateral precerebral artery syndromes
	G452	
	G455	Andurosis rugax
	G434	Other transient excepted inchesmin attacks and related
	G458	Sund
	G450	Transient corebral ischaomic attack, upspecified
	G459	Vaccular avadromoa of brain in corebravecular diaceses
	G40	Vasculai Synuloines of brain in cerebiovasculai diseases
	G460	Antonio cerebral artery syndrome
	G461A	Anterior cerebral artery syndrome
	G462A	Posterior cerebrai artery syndrome
	G463A	Brain stem stroke syndrome
ICD10	G464A	Cerebellar stroke syndrome
ICD10	G465A	Pure motor lacunar syndrome
ICD10	G466A	Pure sensory lacunar syndrome
ICD10	G467A	Other lacunar syndromes
ICD10	G468A	Oth vascular syndromes of brain in cerebrovascular dis
HEART FAILURE SYNDROMES		
ICD10	150	Heart failure
ICD10	1500	Congestive heart failure
ICD10	1501	Left ventricular failure
ICD10	1509	Heart failure, unspecified
ICD10	J81	Pulmonary oedema
CARDIOMYOPATHIES		
ICD10	142	Cardiomyopathy
ICD10	1420	Dilated cardiomyopathy
ICD10	1255	Ischaemic cardiomyopathy
ICD10	1421	Obstructive hypertrophic cardiomyopathy
ICD10	1422	Other hypertrophic cardiomyopathy
ICD10	1423	Endomyocardial (eosinophilic) disease
	1424	Endocardial fibroelastosis
	1425	Other restrictive cardiomyopathy
	1426	Alcoholic cardiomyopathy
	1427	Cardiomyonathy due to drugs and other external agents
	1428	Other cardiomyopathies
	1420	Cardiomyopathy unspecified
	1423	Cardiomyopathy, unspecified
	143	Cardiomyopathy in infectious & parasitis diseases CE
	1430A	Cardiomyopathy in metabolic diseases
	1431A	Cardiomyopathy in metabolic diseases
	1432A	Cardiomyopathy in nutritional diseases
	1438A	Cardiomyopathy in other diseases classified elsewhere
SHOCK (NOT ELSEWHERE CLASSF	IED)	
ICD10	R57	Shock, not elsewhere classified
ICD10	R570	Cardiogenic shock
ICD10	R571	Hypovolaemic shock
ICD10	R578	Other shock

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ICD10	R579	Shock, unspecified
HYPERTENSION AND RELATED COI	NDITIONS	
ICD10	l11	Hypertensive heart disease
ICD10	l110	Hypertensive heart disease with (congestive) heart failure
ICD10	1119	Hypertensive heart disease without (conges) heart failure
ICD10	112	Hypertensive renal disease
ICD10	1120	Hypertensive renal disease with renal failure
ICD10	1129	Hypertensive renal disease without renal failure
ICD10	113	Hypertensive heart and renal disease
ICD10	1130	Hypertens heart and renal dis with (conges) heart failure
ICD10	1131	Hypertensive heart and renal disease with renal failure
ICD10	1132	Hyper heart and renal dis both (cong) heart and renal fail
ICD10	1139	Hypertensive heart and renal disease, unspecified
ICD10	115	Secondary hypertension
ICD10	1150	Renovascular hypertension
ICD10	1151	Hypertension secondary to other renal disorders
ICD10	1152	Hypertension secondary to endocrine disorders
ICD10	1158	Other secondary hypertension
ICD10	1674	Hypertensive encephalopathy
ICD10	1159	Secondary hypertension, unspecified
HEART VALVE DISORERS AND REL	ATED CONDITIO	NS
ICD10	100X	Rheumatic fever without mention of heart involvement
ICD10	101	Rheumatic fever with heart involvement
ICD10	1010	Acute rheumatic pericarditis
ICD10	1011	Acute rheumatic endocarditis
ICD10	1012	Acute rheumatic myocarditis
ICD10	1018	Other acute rheumatic heart disease
ICD10	1019	Acute rheumatic heart disease, unspecified
ICD10	102	Rheumatic chorea
ICD10	1020	Rheumatic chorea with heart involvement
ICD10	1029	Rheumatic chorea without heart involvement
ICD10	105	Rheumatic mitral valve diseases
ICD10	1050	Mitral stenosis
ICD10	1051	Rheumatic mitral insufficiency
ICD10	1052	Mitral stenosis with insufficiency
ICD10	1058	Other mitral valve diseases
ICD10	1059	Mitral valve disease, unspecified
ICD10	134	Nonrheumatic mitral valve disorders
ICD10	1340	Mitral (valve) insufficiency
ICD10	1341	Mitral (valve) prolapse
ICD10	1342	Nonrheumatic mitral (valve) stenosis
ICD10	1348	Other nonrheumatic mitral valve disorders
ICD10	1349	Nonrheumatic mitral valve disorder, unspecified
ICD10	135	Nonrheumatic aortic valve disorders
ICD10	1350	Aortic (valve) stenosis
ICD10	1351	Aortic (valve) insufficiency
ICD10	1352	Aortic (valve) stenosis with insufficiency
ICD10	1358	Other aortic valve disorders
ICD10	1359	Aortic valve disorder, unspecified
ICD10	106	Rheumatic aortic valve diseases

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ICD10	1060	Rheumatic aortic stenosis
ICD10	1061	Rheumatic aortic insufficiency
ICD10	1062	Rheumatic aortic stenosis with insufficiency
ICD10	1068	Other rheumatic aortic valve diseases
ICD10	1069	Rheumatic aortic valve disease, unspecified
ICD10	107	Rheumatic tricuspid valve diseases
ICD10	1070	Tricuspid stenosis
ICD10	1071	Tricuspid insufficiency
ICD10	1072	Tricuspid stenosis with insufficiency
ICD10	1078	Other tricuspid valve diseases
ICD10	1079	Tricuspid valve disease, unspecified
ICD10	136	Nonrheumatic tricuspid valve disorders
ICD10	1360	Nonrheumatic tricuspid (valve) stenosis
ICD10	1361	Nonrheumatic tricuspid (valve) insufficiency
ICD10	1362	Nonrheumatic tricuspid (valve) stenosis with insufficiency
ICD10	1368	Other nonrheumatic tricuspid valve disorders
ICD10	1369	Nonrheumatic tricuspid valve disorder, unspecified
ICD10	108	Multiple valve diseases
ICD10	1080	Disorders of both mitral and aortic valves
ICD10	1081	Disorders of both mitral and tricuspid valves
ICD10	1082	Disorders of both agric and tricuspid valves
ICD10	1083	Combined disorders of mitral aortic and tricuspid valves
ICD10	1088	Other multiple valve diseases
ICD10	1089	Multiple valve disease unspecified
ICD10	109	Other rheumatic heart diseases
ICD10	1090	Rheumatic myocarditis
ICD10	1091	Rheumatic diseases of endocardium valve unspecified
ICD10	1092	Chronic rheumatic pericarditis
ICD10	1098	Other specified rheumatic heart diseases
ICD10	1099	Rheumatic heart disease unspecified
ICD10	137	Pulmonary valve disorders
ICD10	1370	Pulmonary valve stenosis
ICD10	1371	Pulmonary valve insufficiency
ICD10	1372	Pulmonary valve stenosis with insufficiency
ICD10	1378	Other pulmonary valve disorders
	1379	Pulmonary valve disorder unspecified
	1390A	Mitral valve disorders in diseases classified elsewhere
	1391 A	Aortic valve disorders in diseases classified elsewhere
	13020	Tricuspid valve disorders in diseases classified elsewhere
10010	1002A	Pulmonary valve disorders in diseases classified
ICD10	1393A	elsewhere
ICD10	I394A	Multiple valve disorders in diseases classified elsewhere
		· · · · · · · · · · · · · · · · · · ·
PULMONARY CIRCULATORY	DISEASE	
ICD10	126	Pulmonary embolism
ICD10	1260	Pulmonary embolism with mention of acute cor pulmonale
		Pulmonary embolism without mention of acute cor
ICD10	1269	pulmonale
ICD10	127	Other pulmonary heart diseases
ICD10	1270	Primary pulmonary hypertension
ICD10	1271	Kyphoscoliotic heart disease
ICD10	1278	Other specified pulmonary heart diseases

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ICD10	1279	Pulmonary heart disease, unspecified
ICD10	128	Other diseases of pulmonary vessels
ICD10	1280	Arteriovenous fistula of pulmonary vessels
ICD10	1281	Aneurysm of pulmonary artery
ICD10	1288	Other specified diseases of pulmonary vessels
	1280	Disease of pulmonary vessels unspecified
	1209	Disease of pullionary vessels, unspecified
PERICARDIAL DISEASES		
ICD10	130	Acute pericarditis
ICD10	1300	Acute nonspecific idiopathic pericarditis
ICD10	1301	
	1308	Other forms of acute pericarditis
	1300	
	1303	Active pencardinas, unspecified
	131	Chronic adhesive pericerditis
	1310	Chronic adhesive pericarditis
	1011	Chronic constitutive perical dits
	1312	Device reliance of the second se
	1313	Pericardial effusion (noninflammatory)
	1318	Other specified diseases of pericardium
ICD10	1319	Disease of pericardium, unspecified
ICD10	132	Pericarditis in diseases classified elsewhere
ICD10	1320A	Pericarditis in bacterial diseases classified elsewhere
ICD10	I321A	Pericarditis in other infectious and parasitic diseases EC
ICD10	1328A	Pericarditis in other diseases classified elsewhere
	CTIONS	
ENDOCARDITIS AND CARDIAC INFE		Agute and subscute and coorditie
	100	Acute and subacute infactive and coorditie
	1330	Acute and subacute infective endocarditis
	1398A	Endocarditis, valve unspec, in diseases class elsewhere
	1339	Acute endocarditis, unspecified
ICD10	138X	Endocarditis, valve unspecified
ICD10	139	Endocarditis and heart valve disorders in diseases EC
ICD10	1520A	Other heart disorders in bacterial diseases EC
ICD10	I521A	Oth heart disorders in oth infectious and parasitic dis EC
ICD10	1980A	Cardiovascular syphilis
ICD10	I981A	Cardiovascular disorder other infectious and parasitic dis
MYOCARDITIS		
	140	Acute myocarditis
	1400	Infective myocarditis
	1400	
	1401	Other coute muccorditie
	1400	
	1409	Acute myocardilis, unspecified alexades
	141	Myocarditis in diseases classified elsewhere
	1410A	Myocarditis in bacterial diseases classified elsewhere
ICD10	I411A	Myocarditis in viral diseases classified elsewhere
ICD10	1412A	Myocarditis in other infectious and parasitic diseases EC
ICD10	1514	Myocarditis, unspecified
ICD10	I418A	Myocarditis in other diseases classified elsewhere
CARDIAC CONDUCTING SYSTEM D	ISFASE	SE
	1441	Atrioventricular block second degree
		Anoventicular block, second degree
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ICD10	1442	Atrioventricular block, complete
CARDIAC ARREST		
ICD10	I46	Cardiac arrest
ICD10	1460	Cardiac arrest with successful resuscitation
ICD10	1461	Sudden cardiac death, so described
ICD10	1469	Cardiac arrest, unspecified
CARDIAC ARRYTHMIAS		
ICD10	147	Paroxysmal tachycardia
ICD10	1470	Re-entry ventricular arrhythmia
ICD10	1471	Supraventricular tachycardia
ICD10	1472	Ventricular tachycardia
ICD10	1479	Paroxysmal tachycardia unspecified
	148X	Atrial fibrillation and flutter
	1407	Athar hormation and hutter
	149	Ventricular fibrillation and flutter
	1490	
	1490	Sick sinus syndrome
	1498	Other specified cardiac armythmias
ICD10	1499	Cardiac arrnythmia, unspecified
DISEASES OF THE AORTA		
ICD10	171	Aortic aneurysm and dissection
ICD10	1710	Dissection of aorta [any part]
ICD10	1711	Thoracic aortic aneurysm, ruptured
ICD10	1712	Thoracic aortic aneurysm, without mention of rupture
ICD10	1713	Abdominal aortic aneurysm, ruptured
ICD10	1714	Abdominal aortic aneurysm, without mention of rupture
ICD10	1715	Thoracoabdominal aortic aneurysm, ruptured
ICD10	1716	rupture
ICD10	1718	Aortic aneurysm of unspecified site ruptured
ICD10	1719	Aortic aneurysm of unspec site without mention of rupture
ICD10	172	Other aneurysm
	17904	Aneurysm of aorta in diseases classified elsewhere
	1701Δ	Anticity sin of donta in discusses classified elsewhere
	11017	
PERIPHERAL ARTERIAL AND VENO	US DISEASES	
ICD10	1702	Atherosclerosis of arteries of extremities
ICD10	1708	Atherosclerosis of other arteries
ICD10	1720	Aneurysm of carotid artery
ICD10	1721	Aneurysm of artery of upper extremity
ICD10	1722	Aneurysm of renal artery
ICD10	1723	Aneurysm of iliac artery
ICD10	1724	Aneurysm of artery of lower extremity
ICD10	1728	Aneurysm of other specified arteries
ICD10	1729	Aneurysm of unspecified site
ICD10	1730	Raynaud's syndrome
ICD10	1731	Thromboangiitis obliterans [Buerger]
ICD10	1738	Other specified peripheral vascular diseases
ICD10	1739	Peripheral vascular disease, unspecified
		-

ICD10	174	Arterial embolism and thrombosis
ICD10	1740	Embolism and thrombosis of abdominal aorta
105 / 0		Embolism and thrombosis of other and unspec parts of
ICD10	1741	aorta
ICD10	1742	Embolism and thrombosis of arteries of upper extremities
ICD10	1743	Embolism and thrombosis of arteries of lower extremities Embolism and thrombosis of arteries of extremities,
ICD10	1744	unspec
ICD10	1745	Embolism and thrombosis of iliac artery
ICD10	1748	Embolism and thrombosis of other arteries
ICD10	1749	Embolism and thrombosis of unspecified artery
ICD10	177	Other disorders of arteries and arterioles
ICD10	1770	Arteriovenous fistula, acquired
ICD10	1771	Stricture of artery
ICD10	1772	Rupture of artery
ICD10	1776	Arteritis, unspecified
ICD10	1778	Other specified disorders of arteries and arterioles
ICD10	180	Phlebitis and thrombophlebitis
ICD10	1800	Phlebitis/thrombophlebitis superfic vessels low extremties
ICD10	1801	Phlebitis and thrombophlebitis of femoral vein
ICD10	1802	Phlebitis/thrombophlebitis oth deep vessels low extremties
		Phlebitis and thrombophlebitis of lower extremities,
ICD10	1803	unspec
ICD10	1808	Phlebitis and thrombophlebitis of other sites
ICD10	1809	Phlebitis and thrombophlebitis of unspecified site
ICD10	182	Other venous embolism and thrombosis
ICD10	1821	Thrombophlebitis migrans
ICD10	1822	Embolism and thrombosis of vena cava
ICD10	1823	Embolism and thrombosis of renal vein
ICD10	1828	Embolism and thrombosis of other specified veins
ICD10	1829	Embolism and thrombosis of unspecified vein
VARIOUS NON SPECIFIC COD	ES	
ICD10	1515	Myocardial degeneration
ICD10	1516	Cardiovascular disease unspecified
ICD10	1517	Cardiomegaly
ICD10	1518	Other ill-defined heart diseases
	1519	Heart disease unspecified
	152	Other heart disorders in diseases classified elsewhere
	152	Complications and ill-defined descriptions of beart disease
	151	Other heart disorders in other diseases classified
ICD10	I528A	elsewhere
ICD10	197	Postprocedural disorders of circulatory system NEC
ICD10	1970	Postcardiotomy syndrome
ICD10	1971	Other functional disturbances following cardiac surgery
ICD10	1978	Other postprocedural disorders of circulatory system NEC
ICD10	1979	Postprocedural disorder of circulatory system upspecified
ICD10	IQR	Other disorders of circulatory system in diseases FC
ICD10	Igrad	Other specified disorders of circulatory system in dis EC
ICD10	IQQX	Other and unspecified disorders of circulatory system in dis 20
	100/1	e the and anopeenied discrete of circulatory system

#### PROCEDURE CODES CARDIAC SURGICAL PROCEDURES

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CORONARY ARTERY SURGERY		
OPCS4.4	K40.1	Saphenous vein graft replacement of one coronary artery
OPCS4.4	K40.2	Saphenous vein graft replacement of two coronary arteries Saphenous vein graft replacement of three coronary
OPCS4.4	K40.3	arteries Saphenous vein graft replacement of four or more
OPCS4.4	K40.4	coronary arteries Other specified saphenous vein graft replacement of
OPCS4.4	K40.8	coronary artery Unspecified saphenous vein graft replacement of coronary
OPCS4.4	K40.9	artery
OPCS4.4	K41.1	Autograft replacement of one coronary artery NEC
OPCS4.4	K41.2	Autograft replacement of two coronary arteries NEC
OPCS4.4	K41.3	Autograft replacement of three coronary arteries NEC Autograft replacement of four or more coronary arteries
OPCS4.4	K41.4	NEC Other specified other autograft replacement of coronary
OPCS4.4	K41.8	artery
OPCS4.4	K41.9	Unspecified other autograft replacement of coronary artery
OPCS4.4	K42.1	Allograft replacement of one coronary artery
OPCS4.4	K42.2	Allograft replacement of two coronary arteries
OPCS4.4	K42.3	Allograft replacement of three coronary arteries
OPCS4.4	K42.4	Allograft replacement of four or more coronary arteries
OPCS4.4	K42.8	Other specified allograft replacement of coronary artery
OPCS4.4	K42.9	Unspecified allograft replacement of coronary artery
OPCS4.4	K43.1	Prosthetic replacement of one coronary artery
OPCS4.4	K43.2	Prosthetic replacement of two coronary arteries
OPCS4.4	K43.3	Prosthetic replacement of three coronary arteries
OPCS4.4	K43.4	Prosthetic replacement of four or more coronary arteries
OPCS4.4	K43.8	Other specified prosthetic replacement of coronary artery
OPCS4.4	K43.9	Unspecified prosthetic replacement of coronary artery
OPCS4.4	K44.1	Replacement of coronary arteries using multiple methods
OPCS4.4	K44.2	Revision of replacement of coronary artery
OPCS4.4	K44.8	Other specified other replacement of coronary artery
OPCS4.4	K44.9	Unspecified other replacement of coronary artery Double anastomosis of mammary arteries to coronary
OPCS4.4	K45.1	arteries Double anastomosis of thoracic arteries to coronary
OPCS4.4	K45.2	arteries NEC Anastomosis of mammary artery to left anterior
OPCS4.4	K45.3	descending coronary artery
OPCS4.4	K45.4	Anastomosis of mammary artery to coronary artery NEC
OPCS4.4	K45.5	Anastomosis of thoracic artery to coronary artery NEC
OPCS4.4	K45.6	Revision of connection of thoracic artery to coronary artery Other specified connection of thoracic artery to coronary
OPCS4.4	K45.8	artery Unspecified connection of thoracic artery to coronary
OPCS4.4	K45.9	artery
OPCS4.4	K46.1	Double implantation of mammary arteries into heart
OPCS4.4	K46.2	Double implantation of thoracic arteries into heart NEC
OPCS4.4	K46.3	Implantation of mammary artery into heart NEC
OPCS4.4	K46.4	Implantation of thoracic artery into heart NEC
OPCS4.4	K46.5	Revision of implantation of thoracic artery into heart

OPCS4.4	K46.8	Other specified other bypass of coronary artery
OPCS4.4	K46.9	Unspecified other bypass of coronary artery
OPCS4.4	K47.1	Endarterectomy of coronary artery
OPCS4.4	K47.2	Repair of arteriovenous fistula of coronary a
OPCS4.4	K47.3	Repair of aneurysm of coronary artery
OPCS4.4	K47.4	Repair of rupture of coronary artery
OPCS4.4	K47.5	Repair of arteriovenous malformation of coronary artery
OPCS4.4	K47.8	Other specified repair of coronary artery
OPCS4.4	K47.9	Unspecified repair of coronary artery
OPCS4.4	K48.1	Transection of muscle-bridge of coronary artery
OPCS4.4	K48.2	Transposition of coronary artery NEC
OPCS4.4	K48.3	Open angioplasty of coronary artery
OPCS4.4	K48.4	Exploration of coronary artery
OPCS4.4	K48.8	Other specified other open operations on coronary artery
OPCS4.4	K48.9	Unspecified other open operations on coronary artery
TRANSPLANTATION PROCEDURES		
OPCS4.4	K01.1	Allotransplantation of heart and lung
OPCS4.4	K01.2	Revision of transplantation of heart and lung
OPCS4.4	K01.8	Other specified transplantation of heart and lung
OPCS4.4	K01.9	Unspecified transplantation of heart and lung
OPCS4.4	K02.1	Allotransplantation of heart NEC
OPCS4.4	K02.2	Xenotransplantation of heart
OPCS4.4	K02.3	Implantation of prosthetic heart
OPCS4.4	K02.4	Piggy back transplantation of heart
OPCS4.4	K02.5	Revision of implantation of prosthetic heart
OPCS4.4	K02.6	Revision of transplantation of heart NEC
OPCS4.4	K02.8	Other specified other transplantation of heart
OPCS4.4	K02.9	Unspecified other transplantation of heart
VALVE CARDIAC SURGERY		
OPCS4.4	K25.1	Allograft replacement of mitral valve
OPCS4.4	K25.2	Xenograft replacement of mitral valve
OPCS4.4	K25.3	Prosthetic replacement of mitral valve
OPCS4.4	K25.4	Replacement of mitral valve NEC
OPCS4.4	K25.5	Mitral valve repair NEC
OPCS4.4	K25.8	Other specified plastic repair of mitral valve
OPCS4.4	K25.9	Unspecified plastic repair of mitral valve
OPCS4.4	K26.1	Allograft replacement of aortic valve
OPCS4.4	K26.2	Xenograft replacement of aortic valve
OPCS4.4	K26.3	Prosthetic replacement of aortic valve
OPCS4.4	K26.4	Replacement of aortic valve NEC
OPCS4.4	K26.5	Aortic valve repair NEC
OPCS4.4	K26.8	Other specified plastic repair of aortic valve
OPCS4.4	K26.9	Unspecified plastic repair of aortic valve
OPCS4.4	K27.1	Allograft replacement of tricuspid valve
OPCS4.4	K27.2	Xenograft replacement of tricuspid valve
OPCS4.4	K27.3	Prosthetic replacement of tricuspid valve
OPCS4.4	K27.4	Replacement of tricuspid valve NEC

Tricuspid valve repair NEC

Repositioning of tricuspid valve

Other specified plastic repair of tricuspid valve

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K27.5

K27.6

K27.8

OPCS4.4	K27.9	Unspecified plastic repair of tricuspid valve
OPCS4.4	K28.1	Allograft replacement of pulmonary valve
OPCS4.4	K28.2	Xenograft replacement of pulmonary valve
OPCS4.4	K28.3	Prosthetic replacement of pulmonary valve
OPCS4.4	K28.4	Replacement of pulmonary valve NEC
OPCS4.4	K28.5	Pulmonary valve repair NEC
OPCS4 4	K28.8	Other specified plastic repair of pulmonary valve
OPCS4 4	K28.9	Linspecified plastic repair of pulmonary valve
OPCS4 4	K29 1	Allograft replacement of valve of heart NEC
OPCS4 4	K29.2	Xenograft replacement of valve of heart NEC
	K20.2	Prosthetic replacement of valve of heart NEC
	K20.0	Replacement of valve of heart NEC
OPCS4.4	K29.4	Replacement of valve of heart NEC
	K29.5	
	K29.0	Deplement of truncel volve
0PC54.4	K29.7	Replacement of truncal valve
	K29.8	Other specified plastic repair of unspecified valve of neart
OPCS4.4	K29.9	Unspecified plastic repair of unspecified valve of heart
OPCS4.4	K30.1	Revision of plastic repair of mitral valve
OPCS4.4	K30.2	Revision of plastic repair of aortic valve
OPCS4.4	K30.3	Revision of plastic repair of tricuspid valve
OPCS4.4	K30.4	Revision of plastic repair of pulmonary valve
OPCS4.4	K30.5	Revision of plastic repair of truncal valve
OPCS4.4	K30.8	Other specified revision of plastic repair of valve of heart
OPCS4.4	K30.9	Unspecified revision of plastic repair of valve of heart
OPCS4.4	K31.1	Open mitral valvotomy
OPCS4.4	K31.2	Open aortic valvotomy
OPCS4.4	K31.3	Open tricuspid valvotomy
OPCS4.4	K31.4	Open pulmonary valvotomy
OPCS4.4	K31.5	Open truncal valvotomy
OPCS4.4	K31.8	Other specified open incision of valve of heart
OPCS4.4	K31.9	Unspecified open incision of valve of heart
OPCS4.4	K32.1	Closed mitral valvotomy
OPCS4.4	K32.2	Closed aortic valvotomy
OPCS4.4	K32.3	Closed tricuspid valvotomy
OPCS4.4	K32.4	Closed pulmonary valvotomy
OPCS4 4	K32.8	Other specified closed incision of valve of heart
OPCS4 4	K32.9	Unspecified closed incision of valve of heart
	102.0	Aortic root replacement using pulmonary valve autograft
OPCS4.4	K33.1	with right ventricle to pulmonary artery valved conduit
		Aortic root replacement using pulmonary valve autograft
		with right ventricle to pulmonary artery valved conduit and
OPCS4.4	K33.2	aortoventriculoplasty
OPCS4.4	K33.3	Aortic root replacement using homograft
OPCS4.4	K33.4	Aortic root replacement using mechanical prosthesis
OPCS4.4	K33.5	Aortic root replacement
OPCS4.4	K33.6	Aortoventriculoplasty with pulmonary valve autograft
OPCS4.4	K33.8	Other specified operations on aortic root
OPCS4.4	K33.9	Unspecified operations on aortic root
OPCS4.4	K34.1	Annuloplasty of mitral valve
OPCS4.4	K34.2	Annuloplasty of tricuspid valve
OPCS4.4	K34 3	Annuloplasty of valve of heart NEC
OPCS4.4	K34 4	Excision of vegetations of valve of heart
OPCS4 4	K34 5	Closure of tricuspid valve
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OPCS4.4	K34.6	Closure of pulmonary valve
OPCS4.4	K34.8	Other specified other open operations on valve of heart
OPCS4.4	K34.9	Unspecified other open operations on valve of heart

#### PERCUTANEOUS CLOSURE OF SEPTAL DEFECTS

		Percutaneous transluminal repair of defect of
OPCS4.4	K13.1	interventricular septum using prosthesis
		Percutaneous transluminal repair of defect of
OPCS4.4	K13.2	interventricular septum NEC
		Percutaneous transluminal repair of defect of interatrial
OPCS4.4	K13.3	septum using prosthesis
		Percutaneous transluminal repair of defect of interatrial
OPCS4.4	K13.4	septum NEC
		Percutaneous transluminal repair of defect of unspecified
OPCS4.4	K13.5	septum using prosthesis
OPCS4.4	K13.8	Other specified transluminal repair of defect of septum
OPCS4.4	K13.9	Unspecified transluminal repair of defect of septum
OPCS4.4	K16.1	Percutaneous transluminal balloon atrial septostomy
OPCS4.4	K16.2	Percutaneous transluminal atrial septostomy NEC
		Percutaneous transluminal atrial septum fenestration
OPCS4.4	K16.3	closure with prosthesis
OPCS4.4	K16.4	Percutaneous transluminal atrial septum fenestration
		Percutaneous transluminal closure of patent oval foramen
OPCS4.4	K16.5	with prosthesis
		Percutaneous transluminal chemical mediated septal
OPCS4.4	K16.6	ablation
		Other specified other therapeutic transluminal operations
OPCS4.4	K16.8	on septum of heart
		Unspecified other therapeutic transluminal operations on
OPCS4.4	K16.9	septum of heart

CARDIAC SURGERY ON CON	NDUCTING SYSTEM	OF HEART
OPCS4.4	K52.1	Open ablation of atrioventricular node
OPCS4.4	K52.2	Epicardial excision of rhythmogenic focus
OPCS4.4	K52.3	Endocardial excision of rhythmogenic focus
OPCS4.4	K52.4	Open division of accessory pathway within heart
OPCS4.4	K52.5	Open division of conducting system of heart NEC
OPCS4.4	K52.6	Incision of tissue in atria
		Other specified open operations on conducting system of
OPCS4.4	K52.8	heart
		Unspecified open operations on conducting system of
OPCS4.4	K52.9	heart
		- 8
OPCS4 A	K5/ 1	Open implantation of ventricular assist device
OPCS4 4	K54.1	Open removal of ventricular assist device
OPCS4 4	K54.8	Other specified open heart assist operations
OPCS4 4	K54.0	Unspecified open heart assist operations
OPCS4 4	K56 1	Transluminal insertion of pulsation balloon into aorta
OPCS4 4	K56 2	Transluminal insertion of beart assist system NEC
	K56 3	Transluminal maintenance of heart assist system NEO
	K56.4	Transluminal maintenance of heart assist system
		Other appointed transluminal boart appoint appretions
0F034.4	N00.0	Other specified transforminal heart assist operations

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OPCS4.4	K56.9	Unspecified transluminal heart assist operations
PERCUTANEOUS VALVE PR	OCEDURES	
OPCS4.4	K35.1	Percutaneous transluminal mitral valvotomv
OPCS4.4	K35.2	Percutaneous transluminal aortic valvotomv
OPCS4.4	K35.3	Percutaneous transluminal tricuspid valvotomy
OPCS4 4	K35 4	Percutaneous transluminal pulmonary valvotomy
OPCS4.4	K35 5	Percutaneous transluminal valvuloplasty
01 004.4	100.0	Percutaneous transluminal valveloplasty
OPCS4.4	K35.6	and dilation
OPCS4.4	K35 7	Percutaneous transluminal pulmonary valve replacement
01 004.4	100.7	Other specified therapeutic transluminal operations on
OPCS4.4	K35.8	valve of heart
	1.0010	Unspecified therapeutic transluminal operations on valve
OPCS4.4	K35.9	of heart
ELECTROPHYSIOLOGY PRO	CEDURES	
		Percutaneous transluminal ablation of atrioventricular
OPCS4.4	K57.1	node
		Percutaneous transluminal ablation of conducting system
OPCS4.4	K57.2	of heart NEC
		Percutaneous transluminal removal of foreign body from
OPCS4.4	K57.3	heart
OPCS4.4	K57.4	Percutaneous transluminal ablation of accessory pathway
OPCS4.4	K57.5	Percutaneous transluminal ablation of atrial wall
OPCS4.4	K57.6	Percutaneous transluminal ablation of ventricular wall
		Percutaneous transluminal ablation for congenital heart
OPCS4.4	K57.7	malformation
		Other specified other therapeutic transluminal operations
OPCS4.4	K57.8	on heart
		Unspecified other therapeutic transluminal operations on
OPCS4.4	K57.9	heart
000044		Percutaneous transluminal mapping of conducting system
OPCS4.4	K58.1	of heart
000044		Percutaneous transiuminal electrophysiological studies on
OPCS4.4	K58.2	conducting system of neart
0PCS4.4	K58.3	Percutaneous transluminal right ventricular biopsy
OPCS4.4	K58.4	Percutaneous transluminal left ventricular biopsy
OPCS4.4	K58.5	Transluminal intracardiac echocardiography
000044		Other specified diagnostic transluminal operations on
OPCS4.4	K58.8	heart
OPCS4.4	K58.9	Unspecified diagnostic transluminal operations on heart
PACEMAKERS AND DEFIBRI	LLATORS	Inclustation of condiculation definitions using one
		Implantation of cardioverter defibriliator using one
OPC34.4	N09.1	electione lean
OPCS4 4	K50 2	electrode leads
OPCS4.4	K59.2	Positing of load of cordioverter defibrilleter
0PCS4.4	N09.3	Resiling of lead of cardioverter defibilitator
0PCS4.4	K59.4	Renewal of cardioverter defibriliator
OPCS4.4	K59.5	Removal of cardioverter defibrillator
		Uther specified cardioverter defibrillator introduced
02634.4	K59.8	through the vein
OPCS/ /	K20 0	the vein
	1.09.9	

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OPCS4.4	K60.1	Implantation of intravenous cardiac pacemaker system
OPCS4.4	K60.2	Resiting of lead of intravenous cardiac pacemaker system
OPCS4.4	K60.3	Renewal of intravenous cardiac pacemaker system
OPCS4.4	K60.4	Removal of intravenous cardiac pacemaker system
		Implantation of intravenous single chamber cardiac
OPCS4.4	K60.5	pacemaker system
		Implantation of intravenous dual chamber cardiac
OPCS4.4	K60.6	pacemaker system
000011		Implantation of intravenous biventricular cardiac
OPCS4.4	K60.7	pacemaker system
	KEO 8	Other specified cardiac pacemaker system introduced
0FC34.4	N00.0	Unspecified cardiac pacemaker system introduced
OPCS4.4	K60 9	through vein
OPCS4 4	K61 1	Implantation of cardiac pacemaker system NEC
OPC S4 4	K61.2	Resiting of lead of cardiac pacemaker system NEC
OPC S4 4	K61 3	Renewal of cardiac pacemaker system NEC
OPCS4.4	K61.4	Renewal of cardiac pacemaker system NEC
OPCS4.4	K01.4	Implantation of single chamber cardiac pacemaker system
OPCS4.4	K01.5	Implantation of dual chamber cardiac pacemaker system
OPCS4.4	K01.0	Implantation of biventricular cardiac pacemaker system
OPCS4.4		Other energified other eardies personalize system
OPCS4.4	K01.8	Uner specified other cardiac pacemaker system
0PC54.4	K01.9	Unspecified other cardiac pacemaker system
		DEC
RIGHT AND LET THEART		Angiocardiography of combination of right and left side of
OPCS4.4	K63.1	heart
OPCS4.4	K63.2	Angiocardiography of right side of heart NEC
OPCS4.4	K63.3	Angiocardiography of left side of heart NEC
OPCS4.4	K63.4	Coronary arteriography using two catheters
OPCS4.4	K63.5	Coronary arteriography using single catheter
OPCS4 4	K63 6	Coronary arteriography NEC
OPCS4 4	K63 8	Other specified contrast radiology of heart
OPCS4 4	K63 9	Unspecified contrast radiology of heart
01 004.4	100.0	Catheterisation of combination of right and left side of
OPCS4.4	K65.1	heart NEC
OPCS4.4	K65.2	Catheterisation of right side of heart NEC
OPCS4.4	K65.3	Catheterisation of left side of heart NEC
		Catheterisation of left side of heart via atrial transeptal
OPCS4.4	K65.4	puncture
OPCS4.4	K65.8	Other specified catheterisation of heart
OPCS4.4	K65.9	Unspecified catheterisation of heart
PERICARDIAL PROCEDUR	ES	
OPCS4.4	K67.1	Excision of lesion of pericardium
OPCS4.4	K67.8	Other specified excision of pericardium
OPCS4.4	K67.9	Unspecified excision of pericardium
OPCS4.4	K68.1	Decompression of cardiac tamponade
OPCS4.4	K68.2	Pericardiocentesis NEC
OPCS4.4	K68.8	Other specified drainage of pericardium
OPCS4.4	K68.9	Unspecified drainage of pericardium
OPCS4.4	K69.1	Freeing of adhesions of pericardium
OPCS4.4	K69.2	Fenestration of pericardium
OPCS4.4	K69.8	Other specified incision of pericardium
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OPCS4.4	K69.9	Unspecified incision of pericardium
OPCS4.4	K71.1	Biopsy of lesion of pericardium
OPCS4.4	K71.2	Repair of pericardium
OPCS4.4	K71.3	Injection of therapeutic substance into pericardium
OPCS4.4	K71.4	Exploration of pericardium
OPCS4.4	K71.8	Other specified other operations on pericardium
OPCS4.4	K77.1	Percutaneous transluminal pericardiocentesis
OPCS4.4	K77.8	Other specified transluminal drainage of pericardium
OPCS4.4	K77.9	Unspecified transluminal drainage of pericardium
OPCS4.4	K71.9	Unspecified other operations on pericardium
CORONARY ANGIOPLASTY P	ROCEDURES	
		Percutaneous transluminal balloon angioplasty and
OPCS4.4	K75.1	insertion of 1-2 drug-eluting stents into coronary artery
		Percutaneous transluminal balloon angioplasty and
		insertion of 3 or more drug-eluting stents into coronary
UPC54.4	K75.2	arrery Derouteneous transluminal balloon engigalecty and
OPCS4 4	K75 3	insertion of 1-2 stents into coronary artery
01034.4	N75.5	Percutaneous transluminal balloon angioplasty and
OPCS4.4	K75 4	insertion of 3 or more stents into coronary artery NEC
01 004.4	10.4	Other specified percutaneous transluminal balloon
OPCS4.4	K75.8	angioplasty and stenting of coronary artery
		Unspecified percutaneous transluminal balloon
OPCS4.4	K75.9	angioplasty and stenting of coronary artery
		Percutaneous transluminal balloon dilation of cardiac
OPCS4.4	K76.1	conduit
OPCS4.4	K76.8	Other specified transluminal operations on cardiac conduit
OPCS4.4	K76.9	Unspecified transluminal operations on cardiac conduit
	1/70 1	i ransiuminal occlusion of left internal mammary aftery
UFC34.4	N/0.1	Side Didition Other specified transluminal operations on internal
OPCS4.4	K78.8	mammary artery side branch
01 004.4	10.0	Unspecified ?? transluminal operations on internal
OPCS4.4	K78.9	mammary artery side branch
		Percutaneous transluminal balloon angioplasty of one
OPCS4.4	K49.1	coronary artery
		Percutaneous transluminal balloon angioplasty of multiple
OPCS4.4	K49.2	coronary arteries
		Percutaneous transluminal balloon angioplasty of bypass
OPCS4.4	K49.3	graft of coronary artery
000011	1440-4	Percutaneous transluminal cutting balloon angioplasty of
OPCS4.4	K49.4	coronary artery
	K10 9	Other specified transiuminal balloon angloplasty of
UFC34.4	K49.0	Linspecified transluminal balloon angioniasty of coronary
OPCS4.4	K49 9	artery
	K50 1	Percutaneous transluminal laser coronary angioplasty
01 004.4	100.1	Percutaneous transluminal coronary thrombolysis using
OPCS4 4	K50.2	streptokinase
		Percutaneous transluminal injection of therapeutic
OPCS4.4	K50.3	substance into coronary artery NEC
OPCS4.4	K50.4	Percutaneous transluminal atherectomy of coronary artery
		Other specified other therapeutic transluminal operations
OPCS4.4	K50.8	on coronary artery
OPCS4.4	K50.9	Unspecified other therapeutic transluminal operations on
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		coronary artery
OPCS4.4	K51.1	Percutaneous transluminal angioscopy
OPCS4.4	K51.2	Intravascular ultrasound of coronary artery
		Other specified diagnostic transluminal operations on
OPCS4.4	K51.8	coronary artery
		Unspecified diagnostic transluminal operations on
OPCS4.4	K51.9	coronary artery

#### VARIOUS NON-SPECIFIC CARDIAC PROCEDURE CODES

OPCS4.4	K53.1	Inspection of valve of heart
OPCS4.4	K53.2	Exploration of heart NEC
OPCS4.4	K53.8	Other specified other incision of heart
OPCS4.4	K53.9	Unspecified other incision of heart
OPCS4.4	K55.1	Ligation of sinus of valsalva
OPCS4.4	K55.2	Open chest massage of heart
OPCS4.4	K55.3	Open removal of cardiac thrombus
OPCS4.4	K55.4	Open removal of cardiac vegetations NEC
OPCS4.4	K66.8	Other specified other operations of heart
OPCS4.4	K66.9	Unspecified other operations on heart

#### CEREBROVASCULAR PROCEDURES

CAROTID ARTERY PROCEDURES		
OPCS4.4	L29.1	Replacement of carotid artery using graft
OPCS4.4	L29.2	Intracranial bypass to carotid artery NEC
OPCS4.4	L29.3	Bypass to carotid artery NEC
000011	1 00 4	Endarterectomy of carotid artery and patch repair of
OPCS4.4	L29.4	carotid artery
OPCS4.4	L29.5	Endarterectomy of carotid artery NEC High-flow interposition extracranial to intracranial bypass
OPCS4.4	L29.6	from external carotid artery to middle cerebral artery Bypass of carotid artery by anastomosis of superficial
OPCS4.4	L29.7	temporal artery to middle cerebral artery
OPCS4.4	L29.8	Other specified reconstruction of carotid artery
OPCS4.4	L29.9	Unspecified reconstruction of carotid artery
OPCS4.4	L30.1	Repair of carotid artery NEC
OPCS4.4	L30.2	Ligation of carotid artery
OPCS4.4	L30.3	Open embolectomy of carotid artery
OPCS4.4	L30.4	Operations on aneurysm of carotid artery
OPCS4.4	L30.5	Operations on carotid body
OPCS4.4	L30.8	Other specified other open operations on carotid artery
OPCS4.4	L30.9	Unspecified other open operations on carotid artery
OPCS4.4	L31.1	Percutaneous transluminal angioplasty of carotid artery
OPCS4.4	L31.2	Arteriography of carotid artery
OPCS4.4	L31.3	Endovascular repair of carotid artery
		Percutaneous transluminal insertion of stent into carotid
OPCS4.4	L31.4	artery
OPCS4.4	L31.8	Other specified transluminal operations on carotid artery
OPCS4.4	L31.9	Unspecified transluminal operations on carotid artery
CEREBRAL ARTERY PROCEDURES		
OPCS4.4	L33.1	Excision of aneurysm of cerebral artery
OPCS4.4	L33.2	Clipping of aneurysm of cerebral artery

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OPCS4 4	133.3	Ligation of aneurysm of cerebral artery NEC
OPCS4 4	1.33.4	Obliteration of aneurysm of cerebral artery NEC
OPCS4 4	1.33.8	Other specified operations on aneurysm of cerebral artery
OPCS4 4	133.9	Unspecified operations on aneurysm of cerebral artery
OPCS4 4	1.34.1	Reconstruction of cerebral artery
OPCS4 4	134.2	Anastomosis of cerebral artery
OPCS4 4	1343	Open embolectomy of cerebral artery
OPCS4 4	1 34 4	Open embolication of cerebral artery
OPCS4 4	134.8	Other specified other open operations on cerebral artery
OPCS4 4	1 34 9	Unspecified other open operations on cerebral artery
OPCS4 4	1 35 1	Percutaneous transluminal embolisation of cerebral artery
OPC S4 4	135.2	Arteriography of cerebral artery
01 004.4	200.2	Percutaneous transluminal insertion of stent into cerebral
OPCS4.4	L35.3	artery
OPCS4.4	L35.8	Other specified transluminal operations on cerebral artery
OPCS4.4	L35.9	Unspecified transluminal operations on cerebral artery
SUBCLAVIAN/VERTEBRAL ARTER	Y PROCEDURES	
OPCS4.4	L37.1	Bypass of subclavian artery NEC
OPCS4.4	L37.2	Endarterectomy of vertebral artery
		Endarterectomy of subclavian artery and patch repair of
OPCS4.4	L37.3	subclavian artery
OPCS4.4	L37.4	Endarterectomy of subclavian artery NEC
OPCS4.4	L37.8	Other specified reconstruction of subclavian artery
OPCS4.4	L37.9	Unspecified reconstruction of subclavian artery
OPCS4.4	L38.1	Repair of subclavian artery NEC
OPCS4.4	L38.2	Ligation of subclavian artery
OPCS4.4	L38.3	Open embolectomy of subclavian artery
OPCS4.4	L38.4	Operations on aneurysm of subclavian artery
OPCS4.4	L38.8	Other specified other open operations on subclavian artery
OPCS4.4	L38.9	Unspecified other open operations on subclavian artery
		Percutaneous transluminal angioplasty of subclavian
OPCS4.4	L39.1	artery
000044		Percutaneous transluminal embolectomy of subclavian
OPCS4.4	L39.2	artery
	1 20 2	ertory
	L39.3	Arteriography of subclavian orteny
OPC34.4	L39.4	Percutaneous transluminal insertion of stent into
OPCS4 4	139.5	subclavian artery
	200.0	Other specified transluminal operations on subclavian
OPCS4.4	L39.8	artery
OPCS4.4	L39.9	Unspecified transluminal operations on subclavian artery
EVACUATION OF INTRACEREBRA	L	
HAEMORRHAGE		
OPCS4.4	A05.2	Evacuation of haematoma from temporal lobe of brain
OPCS4.4	A05.3	Evacuation of haematoma from cerebellum
OPCS4.4	A05 4	Evacuation of intracerebral baematoma NEC
	/\UU.T	

Evacuation of intracerebral haematoma NEC