DIABETIC KETOACIDOSIS (DKA) ADJUDICATION COMMITTEE CHARTER

DAPAGLIFLOZIN

BMS-512148

TYPE 1 DIABETES

Date:

Version: 2.0

DOCUMENT HISTORY

Version	Date of Issue	Summary of Change
2.0		Revised version • Updated Studies in Scope • Preferred terms (MedDRA v19.1) added. • Added updated adjudication forms • Allowance of final review outside of committee meeting for cases were all are in agreement with the exception of definite cases • administrative and verbiage changes in all sections
1.0		Initial version

CHARTER APPROVAL PAGE

Diabetic Ketoacidosis Adjudication Committee (DKAAC)	
, MD, DKAAC Chairman	
Signature	*Date*
AstraZeneca (AZ)	
, MD Type 1 Medical Lead	
Signature	*Date*
Bristol-Myers Squibb (BMS)	
, MD, PhD, Type 1 Medical Lead	
Signature	*Date*

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1 PURPOSE

The Diabetic Ketoacidosis Adjudication Committee (DKAAC) reviews investigator-identified DKA cases in the Type 1 Diabetes (T1DM) dapagliflozin program (see APPENDIX 1 for studies in scope) to confirm whether DKA has occurred according to criteria established in this charter. The DKAAC creates and maintains the DKAAC Charter along with the sponsor, and completes adjudication forms on which it summarizes its assessment. All potential DKA cases reported by Investigators will be adjudicated by the DKAAC.

This Charter describes the structure, roles, and responsibilities of the DKAAC as well as the process and criteria by which potential DKA cases are adjudicated.

Table 1-1: Contributors to Charter

Name	Role
, MD	DKAAC Chairman
, MD	DKAAC Member
, MD	DKAAC Member

2 PURPOSE OF THE DKA ADJUDICATION COMMITTEE

The DKAAC provides independent assessment, by expert physicians blinded to assignments of study drug, of events in the dapagliflozin (T1DM) program (see APPENDIX 1 for studies in scope). The DKAAC will review data from the clinical trials and adjudicate cases in a consistent, unbiased, and uniform manner. Individual adjudicator assessments as well as final group assessments will be recorded on dedicated adjudication forms.

The DKAAC will conduct all of its operations under International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines. **Adjudication will be performed in a blinded fashion:** DKAAC members will remain blinded to the treatment assignments throughout the entire study adjudication process.

3 MEMBERSHIP

All DKAAC members will be physicians with expertise relevant to adjudication of DKA cases.

3.1 Conditions of Membership

The DKAAC members must disclose all potential conflicts of interest, both financial and non-financial. These include but are not limited to: the ownership of any stock and presence of any consultancy arrangement with any pharmaceutical companies, biotech companies, or contract research organizations; serving as an investigator or co-investigator for the studies covered in this charter; holding any relevant patents. BMS and AZ will be responsible for deciding whether consultancies, financial interests, or non-financial interests of the members materially impact on their objectivity. No members of the DKAAC shall purchase or sell any shares of BMS or AZ stock during the course of the studies. Members of the DKAAC will be responsible for advising the sponsor or desginee in writing of any changes in their financial

interests in pharmaceutical companies, biotech companies, or contract research organizations, including consultancies. Members of the DKAAC who develop potential or significant perceived conflicts of interest that materially impact on objectivity will need to resign.

Prior to functioning as a DKAAC member, a signed confidentiality agreement, a curriculum vitae, a disclosure form, and a signed financial agreement must be completed and submitted to the sponsor or designee electronic study files

3.2 Duration and Structure of Membership

DKAAC membership is expected to be for the duration of the studies in scope (see APPENDIX 1). The membership may also cover future trials within this clinical program. Membership in this DKAAC does not preclude membership in other committees that may be constituted in the future for other dapagliflozin studies. The DKAAC members will not be involved as investigators in the trials.

The DKAAC Chairman will document any additions and/or changes in DKAAC personnel. If a member resigns from the DKAAC, the Chair and Sponsor/Designee will choose a replacement in a timely fashion. In the interim, the remaining members will continue to function within the guidelines of the Charter.

3.3 Preparation and Training

The Sponsor/Designee will provide the following information to the DKAAC prior to the first submission of cases for review:

- Overview of the studies in scope
- Protocols for each study and any amendments that occur from there on after
- Explanation of the case package contents, and form utilization, including Reviewer's and Final (consensus) Adjudication forms
- Instructions for submission of adjudication forms and of requests for additional information
- Discussion of adjudication commitment and anticipated workload

The Sponsor/Designee will provide additional information as requested.

3.4 Committee Members

The committee members are listed in Table 3.4-1.

Table 3.4-1: Membership of the Committee

Name	Role	Affiliation and Contact Information (Address/Phone/email)
, MD, F Med Sci	DKAAC Chair	

Table 3.4-1: Membership of the Committee		
Name	**Role**	**Affiliation and Contact Information (Address/Phone/email)**
, MD	DKAAC Member	
, MD	DKAAC Member	;

3.5 Roles and Responsibilities

3.5.1 DKAAC Members

The DKAAC members will be responsible for the following:

- Advise in the development of DKAAC processes and documents.
- Review and adjudicate assigned cases within 2 weeks of receipt (timeframe will be determined based upon agreement with sponsors or designee, such as times of database locks or other set timelines)
- Participate in all meetings of the DKAAC.

3.5.2 DKAAC Chair

The DKAAC Chair will have the following additional responsibilities:

- Conduct all DKAAC meetings
- Approve the final versions of the DKAAC Charter and associated documents
- Ensure overall quality control of the adjudication process
- Prepare meeting minutes
- Complete, sign and date the final (consensus) adjudication form for each case, within 5 business days (or agreed upon timeline with sponsor or designee) of group case review or receipt of individual forms when group case review is not required (see section 4.3.2)

3.5.3 Sponsor/Designee

The Sponsor/Designee* will:

- Identify and approve cases for adjudication based on criteria established in APPENDIX 2. Criteria may include reassessment of a case if new data becomes available. Refer to section 4.1 for further details on identification of cases
- Compile adjudication packages based on available data and submit to the DKAAC for review when package is complete
- Review data in packages to ensure all queries are resolved and that all relevant information needed for adjudication is included if available
- Assist the DKAAC in obtaining additional information (if needed) about cases undergoing evaluation
- Set up all meetings for adjudication based upon number of cases, DMC (data monitoring committee) meeting schedule, study lock schedules, and agreed upon timelines between committee members and sponsor/designee
- Ensure prompt and timely reviews of all DKA cases by committee members
- Ensure proper tracking, finalization, approval and distribution of all DKA documents
- Ensure proper communication on cases to all DKAAC members

* - The Sponsor is AstraZeneca.

4 ADJUDICATION PROCESS

4.1 Identification of Cases

DKA is an expected event in clinical studies in subjects with type 1 diabetes. Subjects and their family members must be aware of the possibility that DKA may occur, the potential signs and symptoms, as well as the dangers associated with DKA. Investigators will identify potential events of DKA at each study visit. Furthermore, because dapagliflozin reduces plasma glucose in an insulin-independent manner, the marked elevation in blood glucose commonly observed with events of DKA may be attenuated. In order to enhance identification of potential DKA events when a subject experiences signs/symptoms consistent with DKA, additional steps to allow the subject to measure blood ketone levels are included in the studies.

Subjects will receive a combined glucose and ketone meter and will be trained in the procedure of conducting blood ketone testing according to the manufacturer's specifications. Subjects will be advised to measure their blood ketones using the glucose and ketone meter provided by the Sponsor/Designee when they have potential symptoms/signs of DKA, including but not limited to: excessive thirst, nausea and vomiting, frequent urination, weakness or fatigue, fever, fruity-scented breath, confusion, and/or consistently elevated blood glucose, and/or during acute illness. Subjects should contact the study site if their blood ketone reading is ≥ 0.6 mmol/l.

Symptoms potentially associated with DKA, blood ketone test results, and relevant risk factors (eg, missed insulin injection, insulin pump malfunction, infection, heart attack, etc) should be recorded in the subject diary. Investigators will identify and discuss potential DKA events with

subjects at each study visit. The blood ketone values should be reviewed by the site to identify any unusual high values, and to confirm that the values (from the glucose and ketone meter's memory and/or from the subject's diary) were obtained from the subject. If finger stick blood ketone and blood glucose values are discordant from glycemic control assessed by the central laboratory or with clinical symptoms, the subject's glucose and ketone meter should be tested and the procedure for using it reviewed with the subject.

When an Investigator identifies a potential DKA event, she/he will document all DKA related symptoms, relevant risk factors, and available laboratory test results (including blood ketone and blood glucose values measured by the ketone/glucose meter) on the DKA eCRF pages and report this event to the Sponsor/Designee. If an investigator decides to delete an event, the sponsor/designee is not obligated to send the event to the adjudication committee.

All of the potential DKA cases reported by Investigators will be sent to the DKAAC for adjudication (as per criteria below). In addition, the Sponsor/Designee will utilize Standardized MedDRA Queries (SMQs) based on a list of pre-defined terms in Medical Dictionary for Regulatory Activities (MedDRA) to identify potential DKA events. The lists of these terms are included in APPENDIX 2. Investigators will further evaluate these cases when queried about these events and if an event is determined to be a potential DKA case, the investigator will complete the DKA eCRF. Any additional potential DKA cases identified by this process will also be sent for adjudication.

All potential DKA cases that occur during the lead-in and blinded treatment periods of studies, and in any subsequent follow-up periods (per protocol or in accordance with Investigator's reporting) will be submitted for adjudication. Cases occurring during the qualification period will NOT be sent for adjudication unless the abnormality persists and worsens during the lead-in or blinded treatment period(s).

An individual subject may have multiple potential DKA occurrences. Adjudication packages will be prepared and submitted to the DKAAC for each individual occurrence when all relevant information has been made available.

4.2 DKA-Related Documents

Adjudication packages will contain available information necessary for adjudication of identified cases. Adjudication packages will be provided by the Sponsor/Designee to the DKAAC and may include, but are not limited to:

- A case submission form and adjudication result forms (individual DKAAC member result forms and a consensus form for the DKAAC chair) - see Figure 4.2-1
- A DKA Adjudication Patient Profile, which will contain:
    - Demographic data (age, gender, race)
    - All concomitant medications
    - Medical history
    - Physical examination abnormalities
    - Subject status

- All AE/SAE data (to include DKA), as applicable
- Safety narrative, when available.
- Study procedures, as applicable.
- Blinded study medication exposure (if study is blinded)
- Lab results

- Copy of SAE associated documents, (eg, hospital/ER admission note, hospital discharge summary, operative and/or procedure notes, etc.) when applicable.
- Copy of other relevant documents (eg, physician progress notes, outpatient facility report, ER discharge summary, ambulance report, etc.), as applicable, or as deemed necessary either by sponsor, or DKAAC member.

NOTE: The sponsor/designee will coordinate translation of source documents as required. All patient identifying information listed on the source will be redacted

The redaction may include but is not limited to the following:

- **Subject's name**
- **Address**
- **Telephone numbers**
- **Medical Record numbers**
- **Family members names**
- **Insurance numbers**
- **Social Security numbers**
- **Date of birth**
- **Redaction of any additional information with regards to local data protection laws**

Notes:

- ***The DKAAC may request additional information regarding dapagliflozin studies at any time. The sponsor/ designee will provide such information within the scope of the outlined studies in this charter in a timely manner.***

Figure 4.2-1: DIABETIC KETOACIDOSIS (DKA) ADJUDICATION

7 ☐ INDIVIDUAL ADJUDICATION FORM

8 ☐ FINAL ADJUDICATION FORM

EVENT ONSET DATE

D D M Y Y

EVENT ONSET TIME

H H M M

ASSESSMENT OF DKA (MARK ONE):

1 ☐ DEFINITE

4 ☐ POSSIBLE

5 ☐ UNLIKELY

IF ASSESSED AS DEFINITE DKA, PLEASE INDICATE SEVERITY (MARK ONE):

1 ☐ MILD

2 ☐ MODERATE

4 ☐ SEVERE

IF ASSESSED AS DEFINITE DKA, PLEASE INDICATE PRIMARY CAUSE (MARK ONE):

430 ☐ INSULIN PUMP FAILURE

421 ☐ MISSED INSULIN DOSE

431 ☐ SEVERE ILLNESS

432 ☐ NOT IDENTIFIED

98 ☐ OTHER (PLEASE SPECIFY):

IF ASSESSED AS DEFINITE DKA, PLEASE INDICATE CONTRIBUTING FACTORS (SELECT ALL THAT APPLY):

430 ☐ INSULIN PUMP FAILURE

421 ☐ MISSED INSULIN DOSE

431 ☐ SEVERE ILLNESS

432 ☐ NOT IDENTIFIED

98 ☐ OTHER (PLEASE SPECIFY):

ADJUDICATOR: SIGNATURE: DATE:

D D M M M Y Y

4.3 Case Review

4.3.1 Individual Case Review

Upon receipt of adjudication packages ("cases") which will be received by all members, each reviewer will independently evaluate the cases (as described in Section 4.4). If additional information is needed, the Sponsor/Designee should be contacted. Upon completion of the initial review, each DKAAC member will complete the *Individual Adjudication form*, scan and email the completed CRF to Sponsor/Designee for review and subsequent imaging and data entry. When adjudicating cases the DKAAC members will follow the diagnostic criteria/severity for DKA below as listed in Section 4.4.1.

If new relevant information regarding a case becomes available after its adjudication is completed, the case can be sent to the reviewers for re-adjudication. Relevant information will be determined on case by case basis by sponsor or designee medical reviewer.

4.3.2 Group Case Review

It is expected that any cases in which the DKAAC members are not in agreement on the Individual Adjudication forms will be discussed by the DKAAC during group case review meetings. The objective is to express the collective assessment of the DKAAC members who reviewed the case. The frequency of the group case review meetings will depend on case occurrence, but are expected to be held approximately every other month or agreed upon timelines, via teleconference. DKAAC meetings will involve the Chair and members of the DKAAC and may consist of open and closed sessions. No cases will be reviewed without at least 2 of the individual case reviewers present. If any member is unable to attend the adjudication meeting, a written summary of that member's adjudication of cases is required.

- The open sessions may be attended by Sponsor/Designee representatives and will generally include issues related to the conduct of the studies.
- The closed session will be attended only by DKAAC members.

In preparation for group case review meetings, each DKAAC member will receive updated information, if applicable, regarding the individual cases to be reviewed. After group case review meetings, the DKAAC Chair will complete and submit to the Sponsor/Designee a *Final Adjudication form* for each case reviewed during the meeting including cases for which members did not conduct detailed discussion due to consensus being established by individual case reviews. When adjudicating cases the DKAA members will follow the diagnostic criteria/severity for DKA below as listed in Section 4.4.1.

In instances where all Individual Adjudication form responses concur for DKA cases that are assessed as **"possibly" or "unlikely**", the Sponsor/Designee will send the individual forms to the DKAAC Chair for review. The DKAAC Chair can determine if further discussion is warranted or if the Final Adjudication form can be completed without further discussion. If any assessments on the individual forms are discrepant, the case should be discussed until a

consensus is reached. All DKA cases that are assessed as "Definite" will be discussed at the adjudication meeting.

4.3.3 Maintaining Records of Meetings

The DKAAC is responsible for preparing the minutes of all DKAAC meetings documenting communication amongst committee members pertaining to a particular DKA case. The DKAAC will forward the meeting minutes to the sponsor or designee who will maintain an official record of any agendas, minutes, attendance, communications with DKAA members and presentations.

4.4 Adjudicator Assessment

4.4.1 Diagnostic Criteria for DKA

The diagnosis of DKA must be based on robust biochemical data. It cannot solely be defined by the degree of ketonaemia or clinical signs and symptoms. It is defined by decompensated diabetes and evidence of ketoacidosis. When completing the adjudication forms, the DKAAC members will express their opinions regarding whether or not this case is a DKA based on the following criteria:

1) Acidosis
    a) Venous pH <7.3
    b) Serum bicarbonate ≤ 18 mEq/L

Well-documented DKA is a DKA event that meets the above criteria, plus one or more of the following signs/symptoms:

- Hyperventilation
- Dehydration
- Depressed consciousness/confusion

4.4.2 Severity Criteria of DKA

For each confirmed case, the DKAAC members will also express their opinions regarding the severity using the criteria[1] described below (Figure 4.4.2-1), if relevant data are available.

Figure 4.4.2-1: Severity Criteria of DKA

	Mild DKA	Moderate DKA	Severe DKA
pH	< 7.3	< 7.2	< 7.1
Serum bicarbonate (mEq/L)	15 - 18	10 to < 15	< 10
Anion gap[a]	> 10	> 12	> 12
Alteration in sensorial or mental obtundation	Alert	Alert/drowsy	Stupor/coma

[a] calculation $(Na^+) - (Cl^- + HCO_3^-)$ (mEq/L)

4.5 Data Management and Archival

Upon receipt of completed result adjudication CRFs from the DKAAC members, both individual and consensus, the sponsor or designee will review the forms for completeness. Data clarification emails will be sent to the DKAAC members for any missing, incomplete or contradictory data reported on the CRFs. Any corrections made to the original form should be initialed and dated by the adjudicator before resubmitting to sponsor or designee.

The Sponsor/designee will not perform assessments of completed adjudication CRF's against case data and definitions in this Charter. It is the responsibility of the DKAAC to ensure that cases are reviewed and assessed in accordance with the definitions provided in this Charter.

Upon receipt of the completed individual and consensus result adjudication CRFs and review by the sponsor or designee, the adjudication CRFs will be imaged and entered into the relevant study and imaging databases in accordance with established data entry processes. All individual and consensus result adjudication CRFs will be entered into the study database with the exception of comments entered by the adjudicators that are not inclusive of the CRF data point collection. (eg, comments entered on the side of the CRF). These comments will remain available via review of the original forms but will not be part of the electronic database.

4.6 Summary of Adjudication Activities and Associated Timelines

Table 4.6-1 summarizes the adjudication-related activities, responsible party and associated turnaround time.

Table 4.6-1: Adjudication Activities and Turnaround Time

Activity	Responsible Party	Turn Around Time
Identify Cases for Adjudication	Sponsor/ Designee	Ongoing
Compile and Send Adjudication Packages	Sponsor/ Designee	Cases will be sent on an ongoing basis according to agreed upon timelines between sponsors, designees and DKAAC members
Ongoing Individual Review of Cases and Completion/ Submission of *Individual Adjudication* Form	DKAAC members	Within 2 weeks of receipt of adjudication packages or as agreed upon between sponsors, designee and DKAAC members
Query for additional information, when applicable	DKAAC members	Within 2 weeks of receipt of adjudication packages or as agreed upon between sponsors, designee and DKAAC members
Periodic group case review/Consensus meetings	DKAAC members	Every other month and/or other requirement
Completion/Submission of Final Adjudication Form	DKAAC Chair	Within 5 business days of group case review/or receipt of individual forms when group case review is not required (see section 4.3.2)

5 COMMUNICATIONS AND SECURITY

Adjudication packages and all documents that are relevant to the adjudication process will be maintained in a secure manner with password protection. Adjudication packages will be accessible or provided to DKAAC members, sponsor or designee in a secure manner. The DKAAC members will be responsible for maintaining confidentiality of all information supplied to them by the Sponsor/Designee, including data and reports, contents of discussions, notes, and minutes of meetings. Although the DKAAC Chair should be kept aware of the potential need to share the minutes in response to a Health Authority request, any and all external communications concerning the dapagliflozin program will be made only by the Sponsor/Designee.

6 BMS/AZ/DESGINEE CONTACTS

Table 6-1: BMS/AZ/Designee Contacts

Name	Role	Affiliation and Contact Information
, MD,PhD	Type 1 Medical Lead, MB102-229, MB 102-230 Medical Monitor	Bristol Myers Squibb
	Associate Director, Clinical Development	Astra-Zeneca
	Study leader AZ protocol D1695C00001	Astra-Zeneca
, MD	Type 1 medical lead for MB 102-230 as of January 2, 2017	Astra-Zeneca
,	Associate Director Pharmacovigilance and Safety Services	ICON

7 ADDENDA AND REVISIONS TO THE DKAAC CHARTER

Any subsequent changes or additions to this DKAAC charter will be made after consultation with the DKAAC members and the Sponsor/Designee. Subsequent versions will be clearly identified with the date of approval and a version number on the cover page.

8 LIST OF APPENDICES

1) AZ/BMS Studies in scope
2) Preferred Terms for identification of cases based on AEs/SAEs data

9 REFERENCES

1 Kitabchi AE, Umpierrez GE, Miles JM, Fisher JN. Hyperglycemic crises in adult patients with diabetes.Diabetes Care. 2009 Jul;32(7):1335-43. doi: 10.2337/dc09-9032.

APPENDIX 1 AZ/BMS STUDIES IN SCOPE

Study Number	Title
MB102-229	A Multicenter, Randomized, Double-Blind, Placebo-controlled, Parallel Group, Phase 3 Study to Evaluate the Efficacy and Safety of Dapagliflozin as an Add-on to Insulin Therapy in Subjects with Type 1 Diabetes Mellitus
MB102-230	A Multicenter, Randomized, Double-Blind, Placebo-controlled, Parallel Group, Phase 3 Study to Evaluate the Efficacy and Safety of Dapagliflozin as an Add-on to Insulin Therapy in Subjects with Type 1 Diabetes Mellitus
D1695C00001	A clinical pharmacology and long term study to evaluate the safety, efficacy, pharmacokinetics and pharmacodynamics of dapagliflozin therapy in combination with insulin in Japanese subjects with type 1 diabetes who have inadequate glycemic control
D1695C00003	TBD
D1695C00004	TBD

Note: Any future studies that are in-scope will be confirmed by AZ/BMS

APPENDIX 2 BMS PREFERRED TERMS (PTS) FOR IDENTIFICATION OF CASES BASED ON AE/SAE DATA

BMS Custom SMQ Name	BMS Custom SMQ Code	MedDRA Preferred Term	MedDRA Preferred Code	Current MedDRA Version Term
SSC_NAME	SSC_CODE	PT_NAME	PT_CODE	VERSION_TERM
[19.0] MB102 Potential DKA	BMS02961	ABDOMINAL DISCOMFORT	10000059	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	ABDOMINAL PAIN	10000081	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	ABDOMINAL PAIN LOWER	10000084	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	ABDOMINAL PAIN UPPER	10000087	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	ABDOMINAL RIGIDITY	10000090	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	ABDOMINAL TENDERNESS	10000097	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	ACETONAEMIA	10000410	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	ACID BASE BALANCE	10000456	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	ACID BASE BALANCE ABNORMAL	10000457	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	ACID-BASE BALANCE DISORDER MIXED	10000483	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	ACIDOSIS	10000486	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	ACIDOSIS HYPERCHLORAEMIC	10000489	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	ACUTE ABDOMEN	10000647	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	ALTERED STATE OF CONSCIOUSNESS	10001854	MedDRA Version 19.0

BMS Custom SMQ Name	BMS Custom SMQ Code	MedDRA Preferred Term	MedDRA Preferred Code	Current MedDRA Version Term
SSC_NAME	SSC_CODE	PT_NAME	PT_CODE	VERSION_TERM
[19.0] MB102 Potential DKA	BMS02961	ANION GAP	10002522	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	ANION GAP ABNORMAL	10002523	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	ANION GAP DECREASED	10002526	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	ANION GAP INCREASED	10002528	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	APALLIC SYNDROME	10002941	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BLOOD BICARBONATE	10005357	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BLOOD BICARBONATE ABNORMAL	10005358	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BLOOD BICARBONATE DECREASED	10005359	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BLOOD BICARBONATE INCREASED	10005360	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BLOOD CHLORIDE	10005416	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BLOOD CHLORIDE ABNORMAL	10005417	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BLOOD CHLORIDE DECREASED	10005419	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BLOOD CHLORIDE INCREASED	10005420	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BLOOD GASES	10005537	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BLOOD GASES ABNORMAL	10005539	MedDRA Version 19.0

BMS Custom SMQ Name	BMS Custom SMQ Code	MedDRA Preferred Term	MedDRA Preferred Code	Current MedDRA Version Term
SSC_NAME	SSC_CODE	PT_NAME	PT_CODE	VERSION_TERM
[19.0] MB102 Potential DKA	BMS02961	BLOOD GLUCOSE	10005553	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BLOOD GLUCOSE ABNORMAL	10005554	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BLOOD GLUCOSE INCREASED	10005557	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BLOOD LACTIC ACID	10005632	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BLOOD LACTIC ACID ABNORMAL	10005633	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BLOOD LACTIC ACID DECREASED	10005634	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BLOOD LACTIC ACID INCREASED	10005635	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BLOOD OSMOLARITY	10005693	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BLOOD OSMOLARITY ABNORMAL	10005694	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BLOOD OSMOLARITY DECREASED	10005696	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BLOOD OSMOLARITY INCREASED	10005697	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BLOOD OSMOLARITY NORMAL	10005698	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BLOOD PH ABNORMAL	10005705	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BLOOD PH DECREASED	10005706	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BLOOD PH INCREASED	10005708	MedDRA Version 19.0

BMS Custom SMQ Name	BMS Custom SMQ Code	MedDRA Preferred Term	MedDRA Preferred Code	Current MedDRA Version Term
SSC_NAME	**SSC_CODE**	**PT_NAME**	**PT_CODE**	**VERSION_TERM**
[19.0] MB102 Potential DKA	BMS02961	BLOOD POTASSIUM	10005721	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BLOOD POTASSIUM ABNORMAL	10005722	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BLOOD POTASSIUM DECREASED	10005724	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BLOOD POTASSIUM INCREASED	10005725	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BLOOD SODIUM	10005799	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BLOOD SODIUM ABNORMAL	10005800	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BLOOD SODIUM DECREASED	10005802	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BLOOD SODIUM INCREASED	10005803	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BREATH ODOUR	10006326	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	CARBON DIOXIDE	10007220	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	CARBON DIOXIDE DECREASED	10007223	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	CARBON DIOXIDE INCREASED	10007225	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	CENTRAL NERVOUS SYSTEM FUNCTION TEST ABNORMAL	10007947	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	CHILLS	10008531	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	CIRCULATORY COLLAPSE	10009192	MedDRA Version 19.0

BMS Custom SMQ Name	BMS Custom SMQ Code	MedDRA Preferred Term	MedDRA Preferred Code	Current MedDRA Version Term
SSC_NAME	SSC_CODE	PT_NAME	PT_CODE	VERSION_TERM
[19.0] MB102 Potential DKA	BMS02961	COMA	10010071	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	DEATH	10011906	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	DEHYDRATION	10012174	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	DEPRESSED LEVEL OF CONSCIOUSNESS	10012373	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	DIABETIC COMA	10012650	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	DIABETIC HYPERGLYCAEMIC COMA	10012668	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	DIABETIC HYPEROSMOLAR COMA	10012669	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	DIABETIC KETOACIDOSIS	10012671	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	DIABETIC KETOACIDOTIC HYPERGLYCAEMIC COMA	10012672	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	DISCOMFORT	10013082	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	DYSPEPSIA	10013946	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	ELECTROENCEPHALOGRAM	10014407	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	ELECTROENCEPHALOGRAM ABNORMAL	10014408	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	ELECTROLYTE IMBALANCE	10014418	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	ENDOCRINE DISORDER	10014695	MedDRA Version 19.0

BMS Custom SMQ Name	BMS Custom SMQ Code	MedDRA Preferred Term	MedDRA Preferred Code	Current MedDRA Version Term
SSC_NAME	SSC_CODE	PT_NAME	PT_CODE	VERSION_TERM
[19.0] MB102 Potential DKA	BMS02961	FATIGUE	10016256	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	FEELING ABNORMAL	10016322	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	FEELING COLD	10016326	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	FEELING DRUNK	10016330	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	FEELING HOT	10016334	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	FEELING JITTERY	10016338	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	FEELING OF RELAXATION	10016352	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	GASTROINTESTINAL PAIN	10017999	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	HANGOVER	10019133	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	HEART RATE ABNORMAL	10019300	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	HEART RATE INCREASED	10019303	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	HEART RATE IRREGULAR	10019304	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	HUNGER	10020466	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	HYPERGLYCAEMIA	10020635	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	HYPERLACTACIDAEMIA	10020660	MedDRA Version 19.0

BMS Custom SMQ Name	BMS Custom SMQ Code	MedDRA Preferred Term	MedDRA Preferred Code	Current MedDRA Version Term
SSC_NAME	SSC_CODE	PT_NAME	PT_CODE	VERSION_TERM
[19.0] MB102 Potential DKA	BMS02961	HYPEROSMOLAR STATE	10020697	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	HYPOTENSION	10021097	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	HYPOVOLAEMIA	10021137	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	HYPOVOLAEMIC SHOCK	10021138	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	INFANTILE COLIC	10021746	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	KETOACIDOSIS	10023379	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	KETONURIA	10023388	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	KETOSIS	10023391	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	KUSSMAUL RESPIRATION	10023499	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	LACTIC ACIDOSIS	10023676	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	LETHARGY	10024264	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	LOSS OF CONSCIOUSNESS	10024855	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	MALAISE	10025482	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	METABOLIC ACIDOSIS	10027417	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	NAUSEA	10028813	MedDRA Version 19.0

BMS Custom SMQ Name	BMS Custom SMQ Code	MedDRA Preferred Term	MedDRA Preferred Code	Current MedDRA Version Term
SSC_NAME	SSC_CODE	PT_NAME	PT_CODE	VERSION_TERM
[19.0] MB102 Potential DKA	BMS02961	OESOPHAGEAL PAIN	10030180	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	ORTHOSTATIC HYPOTENSION	10031127	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	OSMOLAR GAP	10031140	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	OSMOLAR GAP ABNORMAL	10031141	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	OSMOLAR GAP NORMAL	10031142	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	OXYGEN SATURATION	10033316	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	OXYGEN SATURATION ABNORMAL	10033317	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	OXYGEN SATURATION DECREASED	10033318	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	OXYGEN SATURATION INCREASED	10033320	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	PCO2	10034180	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	PCO2 DECREASED	10034181	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	PCO2 INCREASED	10034183	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	PO2	10035766	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	PO2 DECREASED	10035768	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	PO2 INCREASED	10035769	MedDRA Version 19.0

BMS Custom SMQ Name	BMS Custom SMQ Code	MedDRA Preferred Term	MedDRA Preferred Code	Current MedDRA Version Term
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[19.0] MB102 Potential DKA	BMS02961	RETCHING	10038776	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	SEDATION	10039897	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	SENSATION OF BLOOD FLOW	10039996	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	SENSE OF OPPRESSION	10040007	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	SHOCK	10040560	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	SLUGGISHNESS	10041052	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	SOMNOLENCE	10041349	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	STUPOR	10042264	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	SUDDEN DEATH	10042434	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	THIRST	10043458	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	URINE OSMOLARITY	10046652	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	URINE OSMOLARITY DECREASED	10046653	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	URINE OSMOLARITY INCREASED	10046654	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	VOMITING	10047700	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	VOMITING PROJECTILE	10047708	MedDRA Version 19.0

BMS Custom SMQ Name	BMS Custom SMQ Code	MedDRA Preferred Term	MedDRA Preferred Code	Current MedDRA Version Term
SSC_NAME	SSC_CODE	PT_NAME	PT_CODE	VERSION_TERM
[19.0] MB102 Potential DKA	BMS02961	COMA ACIDOTIC	10049037	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	SUDDEN CARDIAC DEATH	10049418	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	ABDOMINAL MIGRAINE	10049714	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BLOOD GLUCOSE FLUCTUATION	10049803	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	CARDIAC DEATH	10049993	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	THIRST DECREASED	10050200	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	OXYGEN SATURATION IMMEASURABLE	10051197	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	ABDOMINAL REBOUND TENDERNESS	10052489	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	TEMPERATURE INTOLERANCE	10057040	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BLOOD KETONE BODY	10057593	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BLOOD KETONE BODY INCREASED	10057594	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BLOOD KETONE BODY DECREASED	10057595	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	URINE KETONE BODY ABSENT	10057596	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	URINE KETONE BODY PRESENT	10057597	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BLOOD KETONE BODY PRESENT	10057598	MedDRA Version 19.0

BMS Custom SMQ Name	BMS Custom SMQ Code	MedDRA Preferred Term	MedDRA Preferred Code	Current MedDRA Version Term
SSC_NAME	**SSC_CODE**	**PT_NAME**	**PT_CODE**	**VERSION_TERM**
[19.0] MB102 Potential DKA	BMS02961	BLOOD KETONE BODY ABSENT	10057600	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	HYPOPERFUSION	10058558	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	ACETONAEMIC VOMITING	10058938	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	PCO2 ABNORMAL	10058982	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	OXYGEN CONSUMPTION DECREASED	10059165	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	OXYGEN CONSUMPTION	10059167	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	OXYGEN CONSUMPTION INCREASED	10059168	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	EARLY SATIETY	10059186	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	URINE KETONE BODY	10059222	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BASE EXCESS	10059961	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BASE EXCESS INCREASED	10059993	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BASE EXCESS DECREASED	10059994	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	URINE LACTIC ACID	10060064	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	URINE LACTIC ACID INCREASED	10060086	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	URINE LACTIC ACID DECREASED	10060087	MedDRA Version 19.0

BMS Custom SMQ Name	BMS Custom SMQ Code	MedDRA Preferred Term	MedDRA Preferred Code	Current MedDRA Version Term
SSC_NAME	SSC_CODE	PT_NAME	PT_CODE	VERSION_TERM
[19.0] MB102 Potential DKA	BMS02961	BASE EXCESS POSITIVE	10060912	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BASE EXCESS NEGATIVE	10060915	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	ABDOMINAL SYMPTOM	10060926	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BLOOD ELECTROLYTES	10061013	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BLOOD ELECTROLYTES ABNORMAL	10061014	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BLOOD ELECTROLYTES NORMAL	10061015	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	METABOLIC FUNCTION TEST ABNORMAL	10061286	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	PH BODY FLUID	10061346	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	FEELING OF BODY TEMPERATURE CHANGE	10061458	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	SENSATION OF FOREIGN BODY	10061549	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	URINE ELECTROLYTES DECREASED	10061579	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BLOOD ELECTROLYTES DECREASED	10061715	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BLOOD ELECTROLYTES INCREASED	10061716	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BLOOD PH	10061724	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	PH BODY FLUID ABNORMAL	10062071	MedDRA Version 19.0

BMS Custom SMQ Name	BMS Custom SMQ Code	MedDRA Preferred Term	MedDRA Preferred Code	Current MedDRA Version Term
SSC_NAME	SSC_CODE	PT_NAME	PT_CODE	VERSION_TERM
[19.0] MB102 Potential DKA	BMS02961	PH BODY FLUID DECREASED	10062072	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	PH BODY FLUID INCREASED	10062073	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	PO2 ABNORMAL	10062087	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	URINE ELECTROLYTES	10062229	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	URINE ELECTROLYTES NORMAL	10062230	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	SPECIFIC GRAVITY BODY FLUID	10062256	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	SPECIFIC GRAVITY BODY FLUID ABNORMAL	10062257	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	SPECIFIC GRAVITY BODY FLUID DECREASED	10062258	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	SPECIFIC GRAVITY BODY FLUID INCREASED	10062259	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	SPECIFIC GRAVITY BODY FLUID NORMAL	10062260	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	ENDOCRINE TOXICITY	10063003	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	BASE EXCESS ABNORMAL	10063336	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	SUDDEN UNEXPLAINED DEATH IN EPILEPSY	10063894	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	CARBON DIOXIDE ABNORMAL	10064156	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	PAO2/FIO2 RATIO DECREASED	10065413	MedDRA Version 19.0

BMS Custom SMQ Name	BMS Custom SMQ Code	MedDRA Preferred Term	MedDRA Preferred Code	Current MedDRA Version Term
SSC_NAME	**SSC_CODE**	**PT_NAME**	**PT_CODE**	**VERSION_TERM**
[19.0] MB102 Potential DKA	BMS02961	REGURGITATION	10067171	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	COMA SCALE ABNORMAL	10069709	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	HYPOINSULINAEMIA	10070070	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	HYPERGLYCAEMIC UNCONSCIOUSNESS	10071286	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	HUMIDITY INTOLERANCE	10072791	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	ORGANIC ACID ANALYSIS ABNORMAL	10072962	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	ORGANIC ACID ANALYSIS	10072963	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	URINE OSMOLARITY NORMAL	10073410	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	HYPEROSMOLAR HYPERGLYCAEMIC STATE	10076413	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	MENTAL FATIGUE	10076757	MedDRA Version 19.0
[19.0] MB102 Potential DKA	BMS02961	TRANSCRANIAL ELECTRICAL MOTOR EVOKED POTENTIAL MONITORING	10077471	MedDRA Version 19.0

SUPPLEMENTARY DATA

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SUPPLEMENTARY DATA

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Supplementary Table S1. Patient demographic and baseline characteristics (full analysis set)

	Dapagliflozin 5 mg (N=259)	**Dapagliflozin 10 mg (N=259)**	**Placebo (N=260)**
Sex, Male, n (%)	111 (42.9)	130 (50.2)	132 (50.8)
Mean age, years (SD)	41.9 (14.1)	42.7 (14.1)	42.7 (13.6)
Body weight, kg (SD)	81.0 (18.4)	82.1 (17.4)	84.4 (18.3)
BMI, kg/m^2 (SD)	28.4 (5.8)	28.2 (5.2)	28.6 (5.3)
Duration of T1D, years (SD)	19.7 (12.0)	19.9 (11.1)	21.2 (12.2)
HbA1c (%), mean (SD)	8.53 (0.71)	8.52 (0.64)	8.53 (0.67)
HbA1c category, n (%)			
≥7.5 to <9.0%	194 (74.9)	198 (76.4)	194 (74.6)
≥9.0 to ≤10.5%	65 (25.1)	61 (23.6)	66 (25.4)
Total insulin dose, IU (SD)	62.1 (44.2)	59.4 (28.2)	63.1 (29.3)
Method of insulin administration, n (%)			
MDI	162 (62.5)	165 (63.7)	165 (63.5)
CSII	97 (37.5)	94 (36.3)	95 (36.5)

BMI, body mass index; CSII, continuous subcutaneous insulin infusion; HbA1c, glycated haemoglobin; MDI, multiple daily injections; T1D, type 1 diabetes; SD, standard deviation.

SUPPLEMENTARY DATA

Supplementary Table S2. Efficacy endpoints at Week 52 (full analysis set)

	Dapagliflozin 5 mg (N=259)	**Dapagliflozin 10 mg (N=259)**	**Placebo (N=260)**
Patients with HbA1c reduction ≥0.5%, %	43.0	45.7	25.3
Odds ratio vs. placebo (95% CI)	2.30 (1.57, 3.39)	2.62 (1.78, 3.86)	-
Patients with HbA1c reduction ≥0.5% and no severe hypoglycaemia, %	40.2	42.1	23.7
Odds ratio vs. placebo (95% CI)	2.22 (1.50, 3.28)	2.45 (1.66, 3.61)	-
Patients with HbA1c <7.0%, %	7.0	5.5	2.7
Odds ratio vs. placebo (95% CI)	2.57 (1.11, 5.98)	2.00 (0.83, 4.79)	-
Adjusted mean change in fasting plasma glucose from baseline to Week 52, mmol/L (SE)	–1.09 (0.28)	–0.88 (0.28)	0.44 (0.28)
Difference vs. placebo (95%CI)	–1.53 (–2.27, –0.79)	–1.32 (–2.06, –0.58)	-
Number of patients with hypertension at baseline	38	40	44
Adjusted mean change in seated systolic blood pressure from baseline to Week 52 in patients with hypertension at baseline, mmHg (SE) [95% CI]	–9.05 (2.14) [–13.28, –4.81]	–13.30 (2.04) [–17.35, –9.26]	–7.92 (2.02) [–11.93, –3.92]
Difference vs. placebo (95%CI)	–1.12 (–6.57, 4.32)	–5.38 (–10.81, 0.04)	-

SUPPLEMENTARY DATA

Supplementary Table S3. Nature of SAEs up to Week 56 (safety analysis set)

Adverse event, n (%)	Dapagliflozin 5 mg (N=277)	Dapagliflozin 10 mg (N=296)	Placebo (N=260)
≥1 Serious adverse events	37 (13.4)	40 (13.5)	30 (11.5)
Metabolism and nutrition disorders	16 (5.8)	18 (6.1)	6 (2.3)
Gastrointestinal disorders	2 (0.7)	6 (2.0)	1 (0.4)
Injury, poisoning and procedural complications	3 (1.1)	5 (1.7)	6 (2.3)
Cardiac disorders	1 (0.4)	2 (0.7)	1 (0.4)
General disorders and administration site conditions	1 (0.4)	3 (1.0)	2 (0.8)
Infections and infestations	5 (1.8)	4 (1.4)	6 (2.3)
Investigations	0	1 (0.3)	0
Musculoskeletal and connective tissue disorders	1 (0.4)	1 (0.3)	3 (1.2)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (1.1)	4 (1.4)	0
Reproductive system and breast disorders	1 (0.4)	1 (0.3)	0
Vascular disorders	0	2 (0.7)	1 (0.4)
Skin and subcutaneous tissue disorders	0	1 (0.3)	0
Endocrine disorders	0	0	1 (0.4)
Eye disorders	2 (0.7)	0	1 (0.4)
Hepatobiliary disorders	1 (0.4)	0	1 (0.4)
Nervous system disorders	2 (0.7)	0	1 (0.4)
Pregnancy, puerperium and perinatal conditions	1 (0.4)	0	0
Renal and urinary disorders	1 (0.4)	0	0
Psychiatric disorders	0	0	1 (0.4)
Respiratory, thoracic and mediastinal disorders	0	0	1 (0.4)

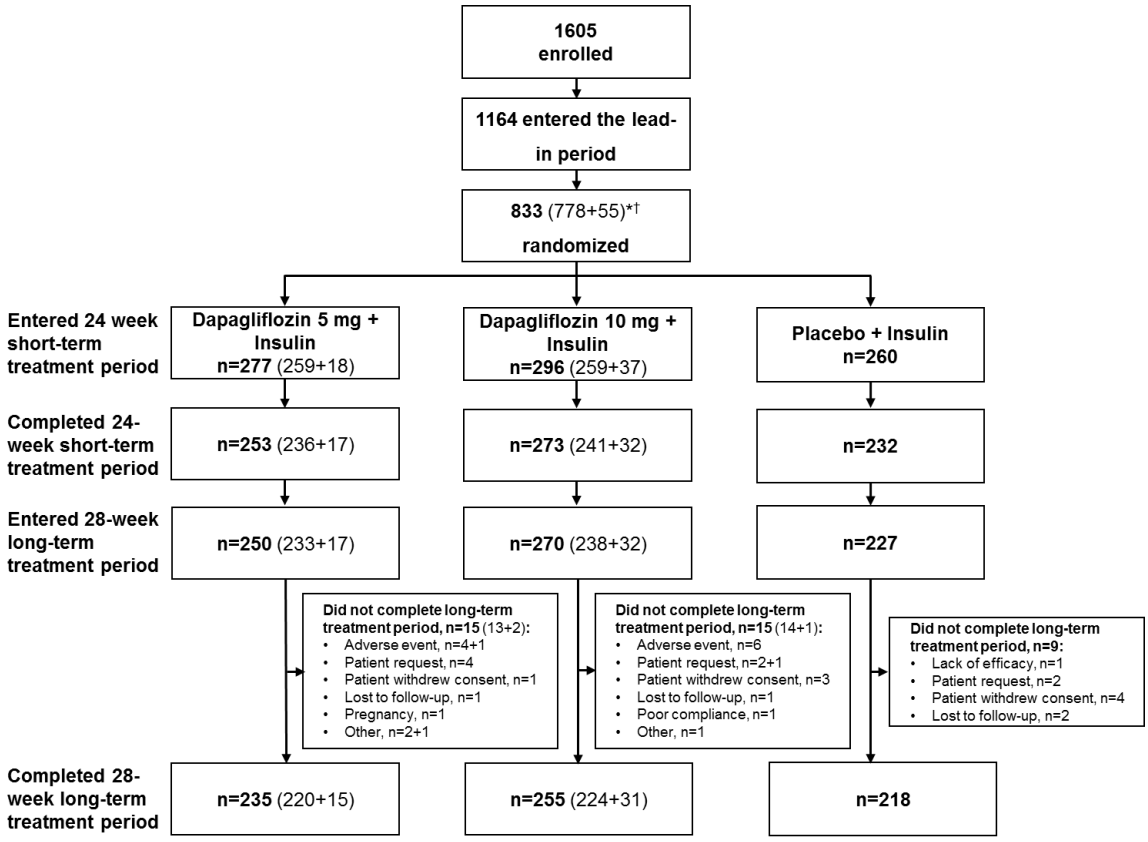
SUPPLEMENTARY DATA

Supplementary Table S4. Vital signs and ECG parameters at baseline and Week 52 (safety analysis set)

Parameter, n (%)	**Dapagliflozin 5 mg (N=277)**	**Dapagliflozin 10 mg (N=296)**	**Placebo (N=260)**
Mean seated systolic blood pressure, mmHg (SD)			
Baseline	121.9 (14.5)	123.1 (15.4)	124.2 (14.7)
Week 52	120.8 (13.9)	120.7 (14.8)	125.7 (15.2)
Mean seated diastolic blood pressure, mmHg (SD)			
Baseline	74.4 (9.1)	74.6 (9.3)	74.7 (9.9)
Week 52	74.2 (8.6)	73.7 (9.1)	75.2 (9.5)
Mean seated heart rate, bpm (SD)			
Baseline	74.5 (11.1)	75.2 (10.7)	74.0 (11.6)
Week 52	75.4 (10.3)	74.5 (10.1)	74.5 (11.1)
Electrocardiogram summary, n (%)			
Baseline			
Normal	225 (81.2)	243 (82.1)	201 (77.3)
Abnormal	52 (18.8)	53 (17.9)	59 (22.7)
Not reported	0	0	0
Week 52			
Normal	216 (78.0)	232 (78.4)	200 (76.9)
Abnormal	41 (14.8)	45 (15.2)	36 (13.8)
Not reported	20 (7.2)	19 (6.4)	24 (9.2)

SUPPLEMENTARY DATA

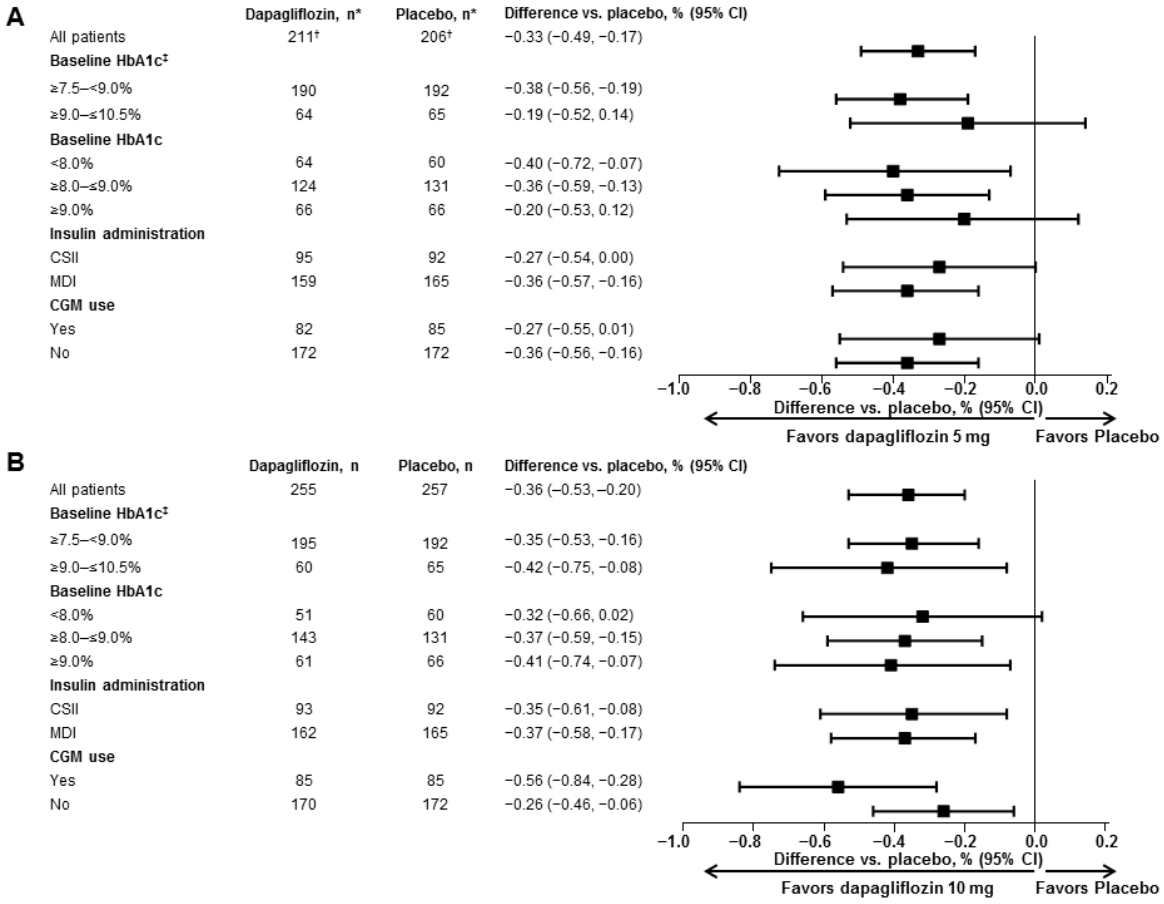
Supplementary Figure S1. Patient disposition



*55 patients were randomly assigned before discovery of an error with the IVRS, these patients are not included in the full analysis set. †One patient was randomized in error and did not receive treatment

SUPPLEMENTARY DATA

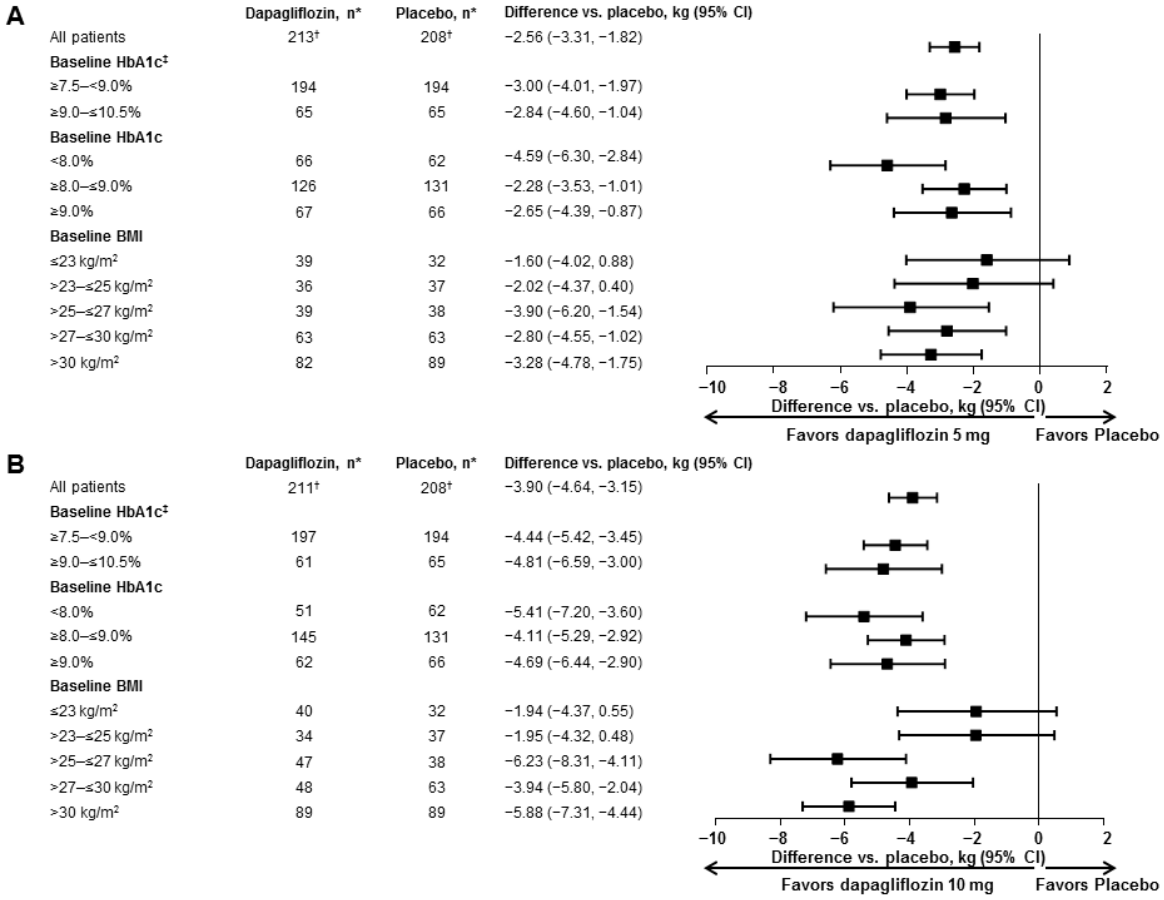
Supplementary Figure S2. Placebo-corrected changes from baseline HbA1c with (A) dapagliflozin 5 mg and (B) dapagliflozin 10 mg; stratified by baseline HbA1c, method of insulin administration, and CGM use (full analysis set)



*n, number of patients in the full analysis set with a baseline and at least one post-baseline value; †n, number of patients in the full analysis set with a baseline and Week 52 value; ‡Randomization stratification factor CGM, continuous glucose monitoring; CI, confidence interval; CSII, continuous subcutaneous insulin infusion; MDI, multiple daily injections.

SUPPLEMENTARY DATA

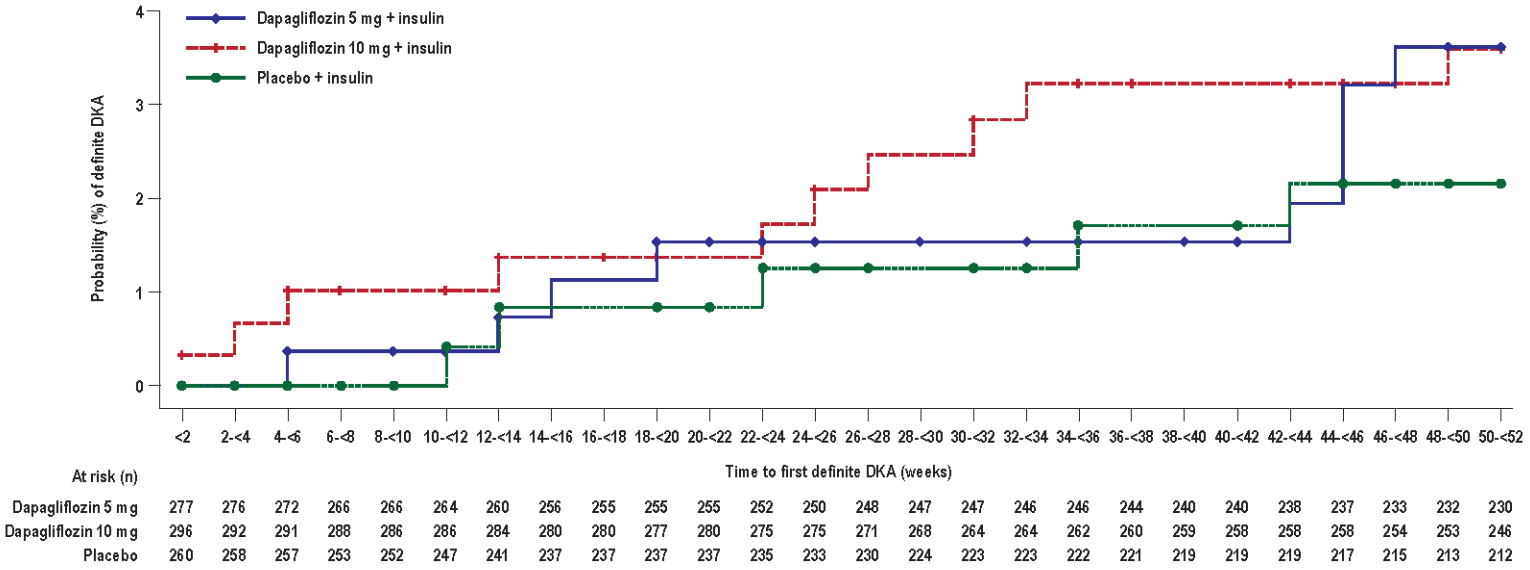
Supplementary Figure S3. Placebo-corrected changes from baseline in body weight with (A) dapagliflozin 5 mg and (B) dapagliflozin 10 mg; stratified by baseline HbA1c and BMI (full analysis set)



*n, number of patients in the full analysis set with a baseline and at least one post-baseline value; †n, number of patients in the full analysis set with a baseline and Week 52 value; ‡Randomization stratification factor BMI, body mass index; CI, confidence interval.

SUPPLEMENTARY DATA

Supplementary Figure S4. Kaplan-Meier plot of time to first definite DKA over the 52 weeks of study (Safety analysis set)



At risk (n)	<2	2-<4	4-<6	6-<8	8-<10	10-<12	12-<14	14-<16	16-<18	18-<20	20-<22	22-<24	24-<26	26-<28	28-<30	30-<32	32-<34	34-<36	36-<38	38-<40	40-<42	42-<44	44-<46	46-<48	48-<50	50-<52
Dapagliflozin 5 mg	277	276	272	266	266	264	260	256	255	255	255	252	250	248	247	247	246	246	244	240	240	238	237	233	232	230
Dapagliflozin 10 mg	296	292	291	288	286	286	284	280	280	277	280	275	275	271	268	264	264	262	260	259	258	258	258	254	253	246
Placebo	260	258	257	253	252	247	241	237	237	237	237	235	233	230	224	223	223	222	221	219	219	219	217	215	213	212

Symbols represent censored observations