Provisional Translation (as of June 2024)
This English version of the Japanese review point is provided for reference purposes only. In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.

Review Point for Software for Peritoneal Dialysis Treatment

Pharmaceuticals and Medical Devices Agency (PMDA)
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Introduction

At the time of making an approval application, information on the review point will be organized and released from medical device programs that have been approved after 2014.

- This review point shall indicate necessary endpoints, etc. for medical devices shown in the specified scope to contribute to the improvement of efficiency in preparation of materials and acceleration of reviews for an approval application.
- This review point shows the concept of review based on the current scientific knowledge, and it shall be reviewed and revised as needed according to future advances in science and technology.

1. Scope of Application

This review point applies to the software for peritoneal dialysis treatment specified in No. 1112 of the Appendix 1 of specially controlled medical devices, controlled medical devices, and general medical devices designated by the Minister of Health, Labour and Welfare according to the stipulations in Article 2, Paragraphs 5 to 7 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (MHLW Ministerial Announcement No. 298 of 2004).

The program is a medical device program that simulates prescription of peritoneal dialysis and supports preparation of a dialysis treatment plan. It is not a substitute for physicians' judgment. Instead of controlling the physical operation of a combined medical device, the program shall only provide treatment parameters for the operation.

2. Endpoints

Medical devices falling under the scope of application shall be evaluated with reference to the items shown in 2.1 to 2.4 below. If another evaluation method is used, its validity shall be explained. It is not necessary to cover all items shown in 2.1 to 2.4, and the corresponding items shall be evaluated.

Even for devices falling under the scope of application, if there is novelty in any of the intended use or effects, shape, structure and principle, and directions for use compared to already-approved medical devices, the novelty shall be appropriately evaluated.

2.1 Data reception function (when data are transferred directly from a combined medical device)

Combined medical devices and treatment information (including test results) of users thereof (hereinafter referred to as "patients") and the means of receiving data in the program shall be clarified, and the program shall be able to receive data appropriately.

2.2 Calculation/display function of arithmetic estimation items related to residual renal function/peritoneal function

It shall be possible to calculate/display arithmetic estimation items related to residual renal function, peritoneal function, etc. using a calculation formula based on the patient treatment information (including test results).

- Explain the validity of making an estimation based on the calculation algorithm in Japan through papers, treatment guidelines, etc. to see whether the calculation algorithm is equivalent to that in the existing program.

2.3 Prescription simulation function

It shall be possible to calculate/display dialysis criteria (dialysis dose, water removal, etc.) according to treatment parameters based on patient treatment information, residual renal function/peritoneal function, etc. And/or it shall be possible to calculate/display treatment parameters depending on the target dialysis criteria.

1) Using the sample data as the method for demonstrating the validity of the "prescription simulation function," explain that appropriate treatment parameters are output for the target dialysis dose/water removal, and/or dialysis dose/water removal are output for the treatment parameters. Specifically, it is acceptable to demonstrate the equivalence by comparing with the results calculated by the existing calculation algorithm.
2) If an abnormal value that cannot be calculated by the program is entered, evaluate the error display function (calculation results cannot be output).

2.4 Prescription preparation, modification and transmission function (when transferring prescription data directly to a combined medical device)

It is evaluated that a prescription such as treatment parameters of a combined automated peritoneal dialysis system, etc. can be set and that treatment parameters of a combined automated peritoneal dialysis system, etc. can be set/changed by the set prescription. At that time, the means of setting prescriptions and configurable treatment parameters for the combined automatic peritoneal dialysis system, etc. shall be clarified.

- It is necessary to confirm whether patients themselves are unable to change prescriptions without the management or guidance of healthcare professionals.

3. Points to Consider for Preparing Application Forms

Each column of the application form and submitted data shall be in accordance with "8. Handling of application for marketing approval" of “Handling of Medical Device Software” (Joint PFSB/MDRMPED Notification No. 1121-33, PFSB/SD Notification No. 1121-1, PFSB/CND Notification No. 1121-29, dated November 21, 2014, by the Counsellor of Minister’s Secretariat, Ministry of Health, Labour and Welfare (the Director of the Medical Device and Regenerative Medicine Evaluation Division), Director of the Safety Division of the Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, and the Director of the Compliance and Narcotics Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare), and "Notice concerning the Publication of Guidance Materials concerning Application for Marketing Approval of Medical Device Software” (Administrative Notice of the Office of Director of the Medical Device and Regenerative Medicine Evaluation Division, Pharmaceutical Safety and.

Environmental Health Bureau, Ministry of Health, Labour and Welfare, dated March 31, 2016).

In addition to the above, items considered to be particularly necessary shall be described with reference to the following items.

3.1 Intended use or effect column

It shall be described that the program applies to the prescription of peritoneal dialysis.

3.2 Shape, structure, and principle column

1) Input/output parameters shall be identified.
   a) Items to be entered/worked by healthcare professionals
   b) Items to be calculated/processed by the program
   c) Items that can be obtained/displayed (when information can be obtained from combined medical devices)
   d) Items that can be transferred (when analysis results can be transferred to combined medical devices)
2) A formula for calculating parameters such as residual renal function/peritoneal function shall be specified.
   a) If the algorithm described above is limited to a particular dialysate or product, the available dialysate shall also be specified.
3) The algorithm for calculating prescription simulation results such as prescription parameters, target dialysis dose, etc., which are dialysis conditions, (calculation formula, papers and treatment guidelines, etc.) shall be specified.
4) If the adjustment of coefficients, setting of upper limits of input information, etc. in the algorithm differ depending on the sex, adult/pediatric, etc. of the target patient, each mode provided in the program shall be specified.

3.3 Directions for use column

(If data can be transmitted/received by the program or if treatment parameters such as an automated peritoneal dialysis system can be set/changed) the combined medical devices shall be specified.

4. Other Matters

1) Programs with only the function to process/handle data for purposes other than diagnosis or treatment or the function to transfer and display data from the medical device are not classified as medical devices.
2) If the setting of the combined automated peritoneal dialysis system can be performed only in the program, and there is no other means to change the setting (for example, treatment parameters can be set in the device itself), the program needs to be a component of the automated peritoneal dialysis system. (Reference:

Q & A 5 of Administrative Notice "Q & A on Handling of Medical Device Software" dated November 25, 2014)

3) It shall be confirmed that measures are taken to reduce the risk of erroneous operation such as mix-up of patients.