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Minister of Health, Labour and Welfare
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Requests for the FY2022 Revision of the Medical Service Fee Schedule for the Control of Antimicrobial Resistance

Globally, antimicrobial resistance (AMR) leads up to 700,000 deaths annually. If current trends continue, an estimated 10 million people could die of AMR-related causes globally every year by 2050. Measures to counter AMR are now advancing around the world. In Japan, approximately 8,000 people already die every year from AMR-related causes, which is more than twice of traffic accidents. Given that Japan's faces an aging population and globalization, the impact of AMR within the country is likely to grow. To address this situation, we request the current medical service fee schedule be revised to reflect the recommendations described below. The views expressed in this request are consistent with those submitted by medical society members of AMR Alliance Japan via the Social Insurance Union of Societies Related to Internal Medicine, which relates to the FY2022 revision of the medical service fee schedule.

1. The revised schedule should facilitate consultations with specialists in infectious disease control.

Based on experiences with the Coronavirus Disease 2019 (COVID-19) pandemic, active consultation with infectious disease specialists and other specialists related to infectious disease control will be essential to address the threat of AMR. However, AMR specific human resources, such as infectious disease specialists, Antimicrobial Stewardship Teams (ASTs), and more, lack sufficient opportunities to advise other departments and healthcare institutions on infectious disease control. Therefore, we request the schedule to be revised to reimburse infectious disease specialists and ASTs for consulting other departments and healthcare institutions on infectious disease control.

2. The revised schedule should support the placement of infectious disease specialists at university and core hospitals.

Infectious disease specialists and infectious disease departments at university and core hospitals lead in many infectious disease control measures, including those for COVID-19. However, only a limited number of university and core hospitals have infectious disease departments or infectious disease specialists on staff. During the schedule revision, we request that measures be included to reimburse university and core hospitals for stationing infectious disease specialists at their facilities.

3. The revised schedule should expand patient eligibility for the premium to support pediatric antimicrobial stewardship measures.

Appropriate antimicrobial usage is important to treat infectious diseases, avoid adverse reactions, and prevent the development of AMR bacteria. In the FY2020 revision of the medical service fee schedule, the targeted age group of the premium to support pediatric antimicrobial stewardship measures was raised from age three and under to age six and under. However, from the perspective of promoting appropriate antimicrobial usage at outpatient clinics, the age limit for this premium is still too restrictive. To promote appropriate antimicrobial usage, we request an expansion of age group eligibility for this premium.

4. The revised schedule should facilitate proactive screening for AMR bacteria.

The spread of AMR bacteria from patients, healthcare workers, and others in healthcare facilities can cause hospital-acquired infections. Despite this, few healthcare institutions test for the presence of AMR strains. Therefore, during the schedule revision, we request that a premium be included for active surveillance using nucleic acid amplification techniques to detect AMR bacteria at time of admission and before surgery.

5. The revised schedule should enable rapid bacterial culture identification testing.

Identifying disease causing organisms enables appropriate antimicrobial treatment, shortens hospital stays, and improves patient outcomes. However, few healthcare institutions conduct bacterial culture identification testing for identifying causative organisms in a timely manner. We request that the schedule revision include a premium for bacterial culture identification testing conducted in a timely manner (in two days or less).

6. The revised schedule should enable rapid antimicrobial susceptibility testing.

Determining the antimicrobial susceptibility of causative organisms leads to appropriate antimicrobial treatment, shortened hospital stays, and improved patient outcomes. However, few healthcare institutions conduct antimicrobial susceptibility tests to determine susceptibility in a timely manner. We request that the schedule revision include a premium for antimicrobial susceptibility testing conducted in a timely manner (in two days or less).

7. The revised schedule should cover therapeutic drug monitoring during outpatient treatment with voriconazole.

Guidelines recommend that therapeutic drug monitoring (TDM) is conducted periodically on the antifungal voriconazole to ensure its effectiveness and safety. However, the current version of the medical service fee schedule only reimburses TDM for voriconazole administered during inpatient treatment. This monitoring is reimbursed through the specified pharmaceutical therapy management premium. Therefore, during the schedule revision, we request that the specified pharmaceutical therapy management premium be expanded to cover TDM on voriconazole when used during outpatient treatment.

8. The revised schedule should facilitate AMR gene detection.

Candida auris is an AMR fungus that exhibits high resistance to antifungals and high virulence, leading to high fatality rates. Its pandemic strains have caused outbreaks in the United States, Europe, and Southeast Asia. Furthermore, *Candida auris* cannot be identified by conventional biochemical tests and requires genetic screening. However, genetic screening kits for *Candida auris* are not commercially available. We request that the schedule is revised to reimburse costs associated with specified genetic screening methods (such as the polymerase chain reaction (PCR) method or the loop-mediated isothermal amplification (LAMP) method). Revising the medical service fee schedule in this manner is likely to advance research and development on genetic screening kits for *Candida auris*.

About AMR Alliance Japan

Established in November 2018, AMR Alliance Japan is an independent platform for multi-stakeholder discussion on AMR control. As of October 2021, its members include the Children and Healthcare Project, MSD K.K., Shionogi & Co., Ltd., Nippon Becton Dickinson Co., Ltd., the Pharmaceutical Society of Japan, the Japan Medical Association, the Japanese Society for Medical Mycology, the Japanese Society of Pharmaceutical Health Care and Sciences, the Japanese Society for Chemotherapy, the Japanese Society of Infection Prevention and Control, the Japanese Society for Pediatric Infectious Diseases, the Japanese Association for Infectious Diseases, the Japan Pharmaceutical Manufacturers Association, the Japanese Society of therapeutic Drug Monitoring, the Japan Society of Hospital Pharmacists, the Japan Pharmaceutical Association, the Japanese Society for Clinical Microbiology, and Pfizer Inc. Health and Global Policy Institute (HGPI) serves as its secretariat.