

White Paper

Shaping the Cardiovascular Disease Access Policy Landscape

South Korea

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Executive summary

In South Korea, cardiovascular disease (CVD) is associated with significant disease burden, with atherosclerotic CVD (ASCVD) among the top 10 leading causes of mortality and disability.¹⁻³ Alarmingly, the economic burden of CVD is growing faster than other leading non-communicable diseases (NCDs) such as oncology.⁴ What stands out in the ASCVD population in South Korea is that most patients are \geq 65 years of age and this population is increasing rapidly, as South Korea is the fastest ageing society in the Organisation for Economic Co-operation and Development (OECD).⁵ With increasing ASCVD prevalence, ASCVD recurrence further adds to disease burden, highlighting the importance of secondary prevention.

There is room for improvement in the management of CVD risk factors in South Korea. Although dyslipidaemia has the highest prevalence and faster growth than other major risk factors, it has been deprioritized in current CVD management plans.⁶ The diagnosis rate for dyslipidaemia is lower than other risk factors, especially in younger patients.⁷ There is also a poor treatment initiation rate for dyslipidaemia compared to hypertension and diabetes, and sub-optimal disease control.⁷⁻⁹ This may be attributed to poor awareness, treatment compliance and follow-up, which calls for more proactive management of dyslipidaemia in Korea.

The government and policy makers should act with urgency to tackle the growing burden on CVD in South Korea and avoid a future public health crisis. Several potential solutions to address ASCVD challenges and unmet needs have been identified, such as:

Development of CVD-specific policies and plans

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Improvement of current screening initiatives

Improved treatment management and **access to long-acting drugs** with fewer side effects These solutions could enhance disease management, treatment and continuity of care, ultimately improving outcomes for patients and drastically reducing the substantial burden of CVD in the coming years.

CVD is currently associated with substantial burden in South Korea. Government and policy makers should act with urgency, as the economic and disease burden of CVD is increasing at high rates in Korea

Introduction

CVD is associated with significant mortality and disability in South Korea, with ASCVDs such as myocardial infarction and stroke contributing to most of the burden.¹⁻³ The considerable disability burden of ASCVD led to the loss of productivity amounting to KRW 11.8 trillion in 2015, with the economic burden growing faster for CVD than other leading NCDs.⁴ Of concern is that most patients with ASCVD in South Korea are ≥65 years of age, and this population has been growing rapidly as South Korea is the fastest ageing society in the OECD.⁵ As ASCVD impacts elderly patients more seriously in terms of mortality and disability, ASCVD spending is largely driven by this age group and is expected to increase considerably.^{1,3}

Although policy makers in South Korea have reacted to the growing disease burden by emphasizing CVD prevention in the National Health Plan 2030 and releasing a CVD management plan (2018-2022),^{10,11} the burden of CVD will continue to rise as gaps still exist in government initiatives for managing CVD risk factors. This is particularly important for dyslipidaemia, which has the highest prevalence and fastest growth of all major risk factors in recent years.⁶

Unless urgent action is taken, the burden of CVD in South Korea is only expected to increase. This white paper will explore the unmet needs associated with the growing burden of CVD and the potential strategies to address these challenges and avoid a future public health crisis. Potential solutions include CVD specific programs, improved treatment management and access to innovative, long-acting drugs.

What is the current state of disease?

South Korea has seen a growing population of patients with CVD over the past 10 years, driven by ASCVD which constitutes 68% of CVD cases.³ The prevalence of ASCVD is 5.2% in South Korea, which is lower than the OECD average (7.7%) and other Asia Pacific (APAC) markets (Japan 8.9%, Australia 7.6%).³ However, CVD has remained the second leading cause of mortality over the last 10 years.² ASCVD is among the top 10 leading causes of mortality and disability in South Korea, contributing to ~50% of CVD deaths (*Figure 1*).^{2,3} In 2019, ischaemic heart disease (IHD) and ischaemic stroke ranked sixth and seventh in the top 10 causes of death and disability, respectively (*Figure 1*).^{2,3}

The considerable disability burden of ASCVD comes with a high price. Loss of productivity due to CVD reached KRW 11.8 trillion in 2015, with economic burden growing faster for CVD between 2006-2015 (6.9%) than other leading NCDs (*Figure 2*).⁴

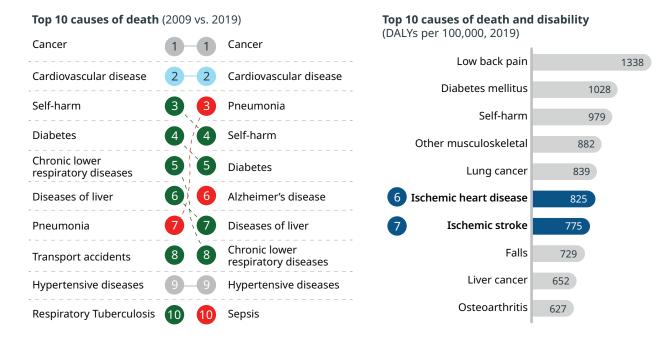


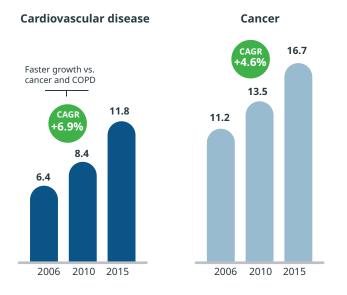
Figure 1: CVD is associated with significant mortality and disability in South Korea

Source: Korean Statistical Information Database (KOSIS), Global Burden of Disease

What stands out in the ASCVD population in South Korea is that most patients are \geq 65 years of age (*Figure 3*).¹ This population has been growing much faster in South

Figure 2: Loss of productivity due to CVD has been growing faster than other leading NCDs

Loss of productivity due to leading NCDs in Korea (KRW trillion, 2006-2015, 9 year CAGR)



Chronic Obstructive Pulmonary Disease



CAGR, compound annual growth rate; COPD, chronic obstructive pulmonary disease

Source: National Health Insurance Research Institute

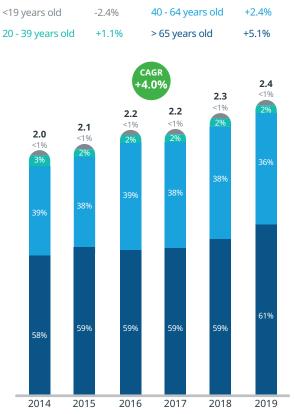
Korea than other markets, as South Korea is the fastest ageing society in the OECD, growing 1.7 times faster than the OECD average.⁵ From 2014 to 2019, there was 5.1% growth in the \geq 65 years age group in South Korea,¹ which is almost double the growth rate seen in other markets (2.3% in Japan and 2.9% in Australia).³ ASCVD also impacts elderly patients more seriously in terms of mortality and disability. In 2019, ischaemic stroke and IHD were the top two leading causes of death and disability for the \geq 65 years age group, with disabilityadjusted life years (DALYs) for the elderly age group higher or on par with other APAC markets (*Figure 4*).³

Figure 3: Estimated number of ASCVD patients in

South Korea by age group

Estimated number of ASCVD patients by age group (Million, 2014-2019)





CAGR, compound annual growth rate Source: HIRA National Health Insurance Database

Figure 4: ASCVD are top 2 causes of mortality and disability in elderly patients

Top 10 causes of death and disability (DALYs per 100,000, 2019)

	65+ age group	
Ischemic stroke	4.222	
IHD	3.811	
Diabetes mellitus	3.677	
Lung cancer	3.645	
Alzheimer's disease	3.389	
COPD	2.548	
Low back pain	2.176	
Lower Respiratory Infections	2.076	
Hearing loss	1.989	
Osteoarthritis	1.928	

COPD, chronic obstructive pulmonary disease Source: Global Burden of Disease As a result of the significant impact on disability, ASCVD spending is largely driven by the \geq 65 years age group; 66% of healthcare spending on ASCVD was attributed to this group in 2019, with a growth of 9.5% from 2013.¹ As this is also the fastest growing age group, the substantial economic burden of CVD is expected to increase further.

With increasing ASCVD prevalence, ASCVD recurrence also adds to disease burden, highlighting the importance of secondary prevention. Despite excellent acute care in South Korea, the long-term case fatality of leading ASCVDs remain high. While South Korea boasts a high success rate of ~99% for percutaneous coronary intervention and ~97% of cases achieving ≤90 min door-to-balloon time for ST elevation myocardial infarction (STEMI), it has been reported that 1 in 10 patients die within 1 year and 2 in 10 die within 3 years (data from 2016).^{12,13} Similarly for ischaemic stroke, ~15% and ~24% of patients die from recurrent stroke within 1 year and 3 years, respectively, and fatality increases significantly with age.¹⁴ These figures are higher than cancers in Korea (25% 5-year mortality for gastric cancer, 24% for colorectal cancer) and indicates that gaps remain in post-ASCVD event, recurrence management.

These data illustrate the significant disease burden that ASCVD poses in South Korea, which is fuelled by an ageing population. Immediate action from the government is needed, while understanding the challenges associated with CVD in order to generate targeted solutions to tackle the growing disease burden.

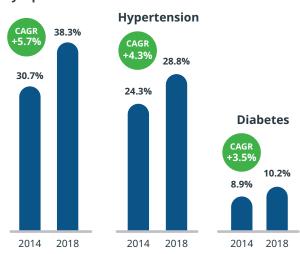
South Korea is the fastest ageing society in the OECD, on its way to become 'most aged societies' by 2040, with 1 in 3 people aged ≥65 years. With the rapid growth of the elderly population, the burden of CVD will only increase unless immediate action is taken.

What are the key unmet needs?

ASCVD is a preventable disease and is a result of many modifiable risk factors, such as dyslipidaemia, hypertension, and diabetes mellitus.¹⁵ These risk factors are the primary drivers for both first and secondary cardiovascular (CV) events, and risk factor modification is a critical component in the reduction of CV deaths.¹⁵

However, there is room for improvement in the management of CVD risk factors in South Korea, especially with the increasing prevalence of major risk factors (*Figure 5*). Of major risk factors, dyslipidaemia has the highest prevalence and fastest growth in recent years.⁶ This is alarming as dyslipidaemia is a key contributor to ASCVD – based on a Korean Heart Study, dyslipidaemia is a major contributor to ischemic heart disease and ischemic stroke.¹⁶

Figure 5: Prevalence of major CVD risk factors (> 20 years of age, 2014 vs. 2018)



Dyslipidaemia

Source: Korean Society of Cardiology, Heart Disease Fact Sheet 2020

Policy makers in South Korea have reacted to the growing ASCVD burden by emphasizing CVD prevention in the National Health Plan 2030 and releasing a CVD management plan (2018-2022).^{10,11} However, targets for dyslipidaemia are only included as sub-targets among 400 other indicators in the National Health Plan.¹¹ Moreover, from a secondary prevention angle, the target for CVD recurrence has been



removed for 2030. Similarly, less emphasis is given to dyslipidaemia compared to other risk factors in the CVD management plan (2018-2022), with prevention initiatives and goals only set for hypertension and diabetes.¹⁰ Dyslipidaemia has also been deprioritized in medical policies and plans such as the National Health Screening Program (NHSP) and the chronic disease management plan. This indicates several policy gaps in tackling dyslipidaemia and secondary prevention.

With dyslipidaemia playing a huge role in the development of ASCVD, dyslipidaemia management should be a high priority in CVD prevention. However, there remains gaps in current government plans and policies which need to be re-looked.

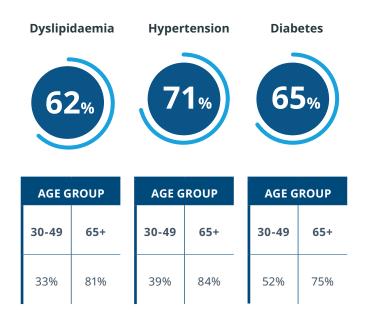
The key unmet needs pertaining to CVD management in South Korea can be grouped into two categories: awareness & diagnosis and treatment & continuity of care.

AWARENESS AND DIAGNOSIS (IDENTIFICATION OF AT-RISK PATIENTS)

There are various lifestyle modification initiatives and programs to promote healthy living and awareness of CVD risk factors in South Korea, covering all age groups and risk factors.¹¹ Regulations are also enforced to address harmful lifestyle habits such as smoking and alcohol intake. To reduce the prevalence of CVD risk factors, there are public awareness and education programs such as the "Know your blood vessel age" campaign.¹⁷

Moreover, South Korea provides free NHSP to people over 20 years of age, with high utilization rate. The program covers all CVD risk factors, which contributes to relatively high diagnosis rates overall in South Korea compared to Japan and Australia.^{7,18-21} However, dyslipidaemia has a lower diagnosis rate than other risk factors and is particularly poor for younger patients. This could be due to a lack of urgency to screen lipid levels. In 2018, the frequency of lipid testing in the NHSP was reduced from every 2 years to every 4 years, and the eligible starting age for women was increased from 20 years to 40 years. In combination with a passive referral process postscreening and lower tendency for younger people to follow up as they are less health conscious, this has resulted in a poor diagnosis rate for dyslipidaemia.⁷

Figure 6: Diagnosis rate of major risk factors and by age group (%, 2019)



Source: Korean National Health & Nutrition Examination Survey 2019

Moreover, there is a lack of awareness among patients who fail to associate their risk factor diagnosis with ASCVD risk. A community health survey conducted in 2013 found that only 25.9% of patients diagnosed with dyslipidaemia were aware of the associated CVD risk.²² This could be attributed to a lack of widespread application of ASCVD risk calculator and one that is specific to the Korean population. Despite various efforts to build a risk prediction model in the past, there is a lack of a consolidated model with real-life application by healthcare professionals in ASCVD prevention and treatment guidelines.^{16,23-25} Although the existing initiatives have achieved some success in raising awareness of ASCVD, the disparity in diagnosis rate between risk factors and age groups calls for a more targeted policy in South Korea.

TREATMENT AND CONTINUITY OF CARE

The disparity between risk factors and age groups remains after diagnosis. Compared to hypertension and diabetes, dyslipidaemia has a poor treatment initiation rate. In 2019, up to 30% of middle-aged patients in South Korea did not receive treatment for dyslipidaemia, which was almost three times higher than diabetes (12%) and hypertension (11%).⁷ This is due to the lack of awareness of the severity of high lipid levels and low perceived benefit of treatment without observed symptoms. Moreover, gaps remain in dyslipidaemia treatment even among 'very high-risk' patients with a history of ASCVD, due to poor awareness of the importance of managing risk factors to reduce second CV events (secondary prevention). Alarmingly, a 2020 study found that only ~60% of patients with newly diagnosed ASCVD were given lipid lowering therapy.²⁶

"There is lower urgency to start treatment without any observed symptoms...Moreover, patients relate high blood preassure to stroke, while awareness around lipid as risk factor remains low".

-Cardiologist at leading hospital

South Korea has the highest pharmaceutical spending on ASCVD risk factors compared to other reimbursed markets in APAC, the UK and Canada.^{3,27} There is also a high proportion of drug expenditure on CVD risk factors with increasing spending per patient, particularly for dyslipidaemia (7.3% increase from 2015 to 2019).²⁸ However, it has been reported that the high drug expenditure and volume of lipid agents consumed has not led to equivalent disease control, with South Korea having the smallest change in mean non-HDL cholesterol level versus Taiwan, Australia, Canada, and the UK within the same time period.^{29,30} This suggests that there are gaps in current treatment management.

"Most doctors in pratice agree that cholesterol LDL-C reduction is key for CVD management. However, there are still gaps in LDL-C control in Korea due to HCP inertia for approapiate treatment and fear of side effects of existing treatment".

-Senior cardiologist at leading hospital

Various studies have also highlighted that disease control rates for dyslipidaemia are sub-optimal and that patients are not achieving their target low-density lipoprotein-cholesterol (LDL-C) level. This is worrying as it is widely established through multiple studies and amongst clinicians that elevated concentrations of LDL-C as a cause of ASCVD. In addition, lowering LDL-C levels produces marked reduction of ASCVD. A nationwide population-based study found that high LDL-C levels were significantly associated with increased risk of myocardial infarction especially among 20-39 aged population, emphasizing the critical need to achieve optimal lipid levels for ASCVD prevention.⁴⁴

It has been reported that less than 50% of patients on treatment achieve optimal LDL-C levels, which reduces further to only ~18% for 'very high-risk' patients.⁸ In another study published in 2020, LDL-C goal attainment rates were reported to be in the range of 9.2–26.3% for 'very high-risk' patients, defined as patients with stroke, acute coronary syndrome, coronary heart disease and peripheral artery disease.⁹ This can be attributed to lack of awareness and urgency to effectively control lipid levels, resulting in late detection of dyslipidaemia, healthcare professional (HCP) inertia for timely and appropriate LDL-C treatment as HCPs deem current levels sufficient, as well as patient reluctance to increase dosage of existing treatment due to side effects. Moreover, a 2020 study reported that physicians underestimated the risk levels of ~72% of patients (mostly very high-risk patients), which further adds to low control rates.³¹

"In some patients treated for >1 disease, I've observed that adherence for dysplipidaemia is lower than hypertension due to varying treatment priority and side effects of existing drugs."

-Senior cardiologist at leading hospital

Furthermore, there is poor treatment compliance for risk factor management, especially for dyslipidaemia caused by lack of effective patient follow-up and monitoring.^{12,18,19} Adherence and persistence rates for dyslipidaemia are problematic at ~42% and ~55%, respectively, with treatment for other risk factors such as hypertension and diabetes taking precedence.^{32,33} While better adherence is observed for secondary prevention (~75% adherence 1 year after stroke), there is room for improvement when compared to other markets such as Japan (80-95%) and the US (91%).^{14,34,35} The points discussed above call for better treatment management and follow-up of CVD risk factors, especially dyslipidaemia. While the government has put forward various initiatives to improve continuity of care, such as the Hypertension Diabetes Registry Management Program (~2009) and Primary-care Chronic disease management program (~2012),³⁶ dyslipidaemia has been excluded. There is also a lack of emphasis on secondary prevention, which is embedded only as an indirect outcome of the programs. All of this suggest that more proactive management of dyslipidaemia is required in Korea.

Despite consistent evidence from academia and clinical practice on the importance of LDL-C lowering in ASCVD reduction, there are clear unmet needs in current management, attributed to gaps in HCP and patient awareness, treatment compliance and follow-up.

What are the potential solutions?

Several solutions and strategies to tackle ASCVD challenges and unmet needs along the patient journey have been identified, particularly for dyslipidaemia. The solutions discussed below could enhance disease management and continuity of care, ultimately improving outcomes for patients with dyslipidaemia.

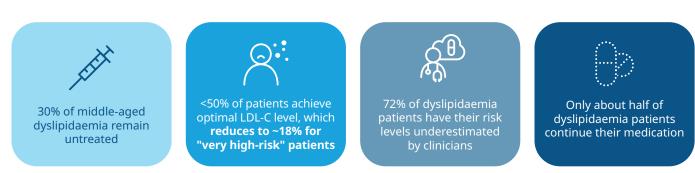
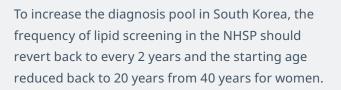


Figure 7: Unmet needs for dyslipidaemia treatment



Case study 1: Improvement of current screening initiatives in South Korea



In Japan, population health screening covers all segments of the population and provides annual checks for all CVD risk factors, including blood pressure, glucose, and cholesterol.³⁷ The main programs include employer-based annual core and secondary check-ups (Ippan kenshin) and annual specific health check-ups for those 40–74 years of age (Tokutei kenshin).



Ippan kenshin: Items for core check-up cover all CVD risk factors. Free secondary health check-ups are provided for patients with high levels of CVD risk factors and doctors provide face-to-face consultations on reducing risk factors

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Tokutei kenshin: Items cover major CVD risk factors and specific health guidance is provided to higher risk patients

Case study 2: Data-driven approach to identify patients that are undiagnosed or untreated

The National Health Service (NHS) in the UK has introduced CVDPREVENT as part of its long-term plan.³⁸ This serves as a national CVD prevention audit, utilizing GP data to identify patients that are not diagnosed or not receiving optimal treatment.

Routinely held GP data covering diagnosis and management of high-risk conditions that cause CVD (including dyslipidaemia, hypertension and diabetes) are automatically extracted to identify patients and offer optimal CVD management. The tool offers local and national reporting in real-time, allowing clinics and primary care networks to identify ways to improve patient outcomes.

A similar approach can be implemented in South Korea, potentially leveraging existing government initiatives such as "MyHealthWay" app which aims at integration of all medical data.

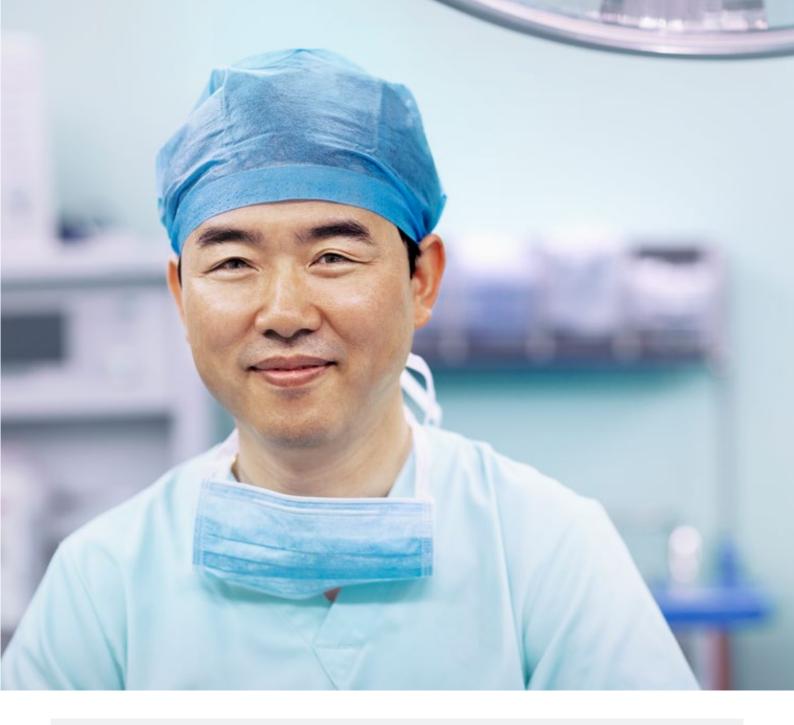
AWARENESS AND DIAGNOSIS (IDENTIFICATION OF AT-RISK PATIENTS)

To increase public urgency, interest, and awareness of CVD risk factors, current screening initiatives in South Korea could be improved (*case study 1*) and a data-driven approach could be utilized to identify undiagnosed or untreated patients (*case study 2*). Moreover, development of a consolidated ASCVD risk prediction model for the South Korean population would also be beneficial. The model could be used by HCPs and/ or applied to NHSP screening data for risk factors to calculate ASCVD risk and raise awareness.

TREATMENT AND CONTINUITY OF CARE

More aggressive national CVD targets could be introduced in South Korea to raise urgency among HCPs for improved disease control. The current CVD plan does not include treatment targets for dyslipidaemia or CVD recurrence, and both could be introduced in the second CVD plan to be released for 2023-2028. Moreover, to improve treatment management for dyslipidaemia, especially for the 'very high-risk' group, the introduction of HCP and patient incentivization programs (*case studies 3 and 4*) and the availability of a long-acting drug which improves patient compliance (*case study 5*) would be beneficial in





Case study 3: HCP incentivization program



The existing primary care chronic disease management program in Korea could be expanded to include dyslipidaemia, and recurrence management could be introduced as a key assessment criterion for incentivization to improve patient monitoring and follow-up. These programs focus on holistic CVD prevention, rather than disease specific outcomes. In the UK, the Quality of Outcomes Framework (QOF) introduced in 2004 is the best-in-class primary care pay-for-performance program, which incentivizes clinics based on assessment indicators such as primary and secondary CVD prevention. 40 Points are awarded to each practice based on their target achievements and financial incentives are paid accordingly. With a GP participation rate of ~99%, the program is highly effective in CVD prevention, resulting in an estimated saving of 11 lives per 100,000 patients with CVD per year.



Case study 4: Patient incentivization program

The National Smoking Cessation Program, which is a population health approach to manage a major risk factor and reduce burden from smokingattributable diseases, is subsidized in South Korea.⁴¹ A similar patient incentivization program could be implemented for ASCVD risk factors, to improve treatment initiation, adherence and persistence.

Case study 5: Introduction of a long-acting drug to improve patient compliance

A long-acting drug with fewer side effects for the treatment of CVD risk factors such as dyslipidaemia could potentially reduce treatment follow-up and monitoring frequency, as well as improve adherence.

Prolia (denosumab) is a first-in-class human monoclonal antibody indicated for the treatment of osteoporosis in post-menopausal women, which is administered by subcutaneous injection every 6 months. Better treatment adherence, compliance and persistence, and reduced side effects with Prolia have been demonstrated through a large scale, crossover study of 250 postmenopausal women.⁴² Prolia was introduced to replace alendronate because it requires a lower frequency of administration, follow-up and monitoring (6-monthly), which helps to minimize hospital visits and drop-out of patients from osteoporosis treatment. Amgen leveraged Prolia's longer duration of action and better side-effect profile to advocate for the inclusion of the drug under the Pharmaceutical Benefits Scheme in Australia.⁴⁴

South Korea. Modelling indicates that the introduction of a long-acting drug for effective LDL-C control could save 11,350 lives, 29,966 quality-adjusted life years (QALYs) and ~US\$965 million over the next 10 years by avoiding major adverse CV events.³⁹

Call to action: what can be done now?

The government and policy makers should take urgent action to address the significant clinical and economic burden of ASCVD in South Korea, which is expected to increase considerably due to the rapidly ageing population. Although policy makers in South Korea have reacted to the burden of CVD by emphasizing CVD prevention in the National Health Plan 2030 and releasing a CVD management plan (2018-2022),^{10,11} the burden will continue to grow as gaps still exist in current policies for managing CVD risk factors. If no immediate steps are taken to address these challenges, there is a risk of a future public health crisis in South Korea.

Actions that can be taken now include the development of CVD policies/programs, improving treatment management, and the introduction of an innovative drug for effective LDL-C control. These solutions are a mix of immediate and long-term strategies. Initiatives to raise public awareness and improve diagnosis will take more time to reap benefits, preparing the population against future disease burden. Meanwhile, improving treatment management through improved follow-up programs or using a long-acting drug that requires reduced frequency of monitoring will serve as an immediate solution to tackle current challenges faced by the growing pool of patients with ASCVD. Potential solutions for the challenges and unmet needs associated with ASCVD must be comprehensive yet targeted, and inclusive of the general public as well as risk groups.

CVD is a costly disease which is associated with significant disability and mortality. However, proactive implementation of CVD-specific programs by the government and policy makers in South Korea could drastically reduce the substantial burden of CVD in the coming years. Modelling indicates that the effective LDL-C reduction could save 29,966 QALYs and ~US\$965 million over the next 10 years.³⁹

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Appendix

A. ICD-10 Code used for CVD & ASCVD definition

DISEASE	ICD-10 CODE
CVD	I00-I79, G45
ASCVD	I20-I25, I63, I65-I69, I70, I73-I74, G45
Ischemic Heart Disease	I20-I25
Ischemic Stroke	I63, G45
Peripheral Arterial Disease	165-169, 170, 173-174

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With thanks to the Novartis team for their contribution and collaboration in the development of this white paper.

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