Annex F: Summary of Equalities Considerations

This equalities impact assessment considers the impact of the NICE appraisal committee's recommendation in the context of the proposed Funding Variation Implementation Plan (IP).

The assessment considers any phasing scenario versus the alternative (90-day implementation for all recommended patient cohorts).

Overview of Obesity

Overweight and obesity (excess weight) affects over 60% of the adult population and places a huge burden on individuals, society and the health and care system. The Global Burden of Disease study placed both poor diet and obesity in the top five risk factors for premature mortality in England. Emerging evidence has demonstrated that people living with obesity are at higher risk of severe illness from COVID-19 infection[i]. Obesity disproportionately impacts different population groups. The main issues are increased prevalence of obesity, reduced access to weight management services, and problems around retention within the services (see **Annex C** for details):

- **Strong relationship between obesity and deprivation** across all age groups for both children and adults.
- **Geographic variation** in obesity prevalence is different for children and adults. London has the highest prevalence of childhood obesity, but the lowest level of excess weight in adults.
- Prevalence **varies by ethnicity** with black children and adults having the highest rate of excess weight.
- People with **severe mental illness** experience significant inequalities, with almost double the rate of obesity as well as reduced take-up of information and obesity-related interventions.
- **People with disabilities** have a higher rate of obesity while at the same time, facing significant barriers in accessing health services.
- While prevalence of overweight and obesity are similar for men and women, **men are less likely to access** weight management services.

<table>
<tr><th>Protected characteristic groups or group facing health inequalities</th><th>Equalities impact considerations</th></tr>
<tr><td>Age: older people; middle years; early years; children and young people.</td><td>The uptake proposal does not propose specific allowances or exclusions for patients based on age. As such, phasing introduction blind of age would be in line with the drug's Marketing Authorisation, with the proposed NICE recommendation and in line with the aim of making the drug available soonest for those with the highest health needs.

Age related data for obesity is below (Health Survey for England, 2019).

<table>
<tr><th></th><th colspan="2">% obese including morbidly obese (2019)</th><th colspan="2">% morbidly obese (2019)</th></tr>
<tr><td>Age</td><td>Male</td><td>Female</td><td>Male</td><td>Female</td></tr>
<tr><td>16-24</td><td>13.7%</td><td>12.0%</td><td>2.0%</td><td>1.9%</td></tr>
<tr><td>25-34</td><td>19.2%</td><td>25.8%</td><td>2.5%</td><td>6.2%</td></tr>
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<tr><td></td><td>
<table>
<tr><td>35-44</td><td>27.3%</td><td>32.7%</td><td>1.9%</td><td>5.7%</td></tr>
<tr><td>45-54</td><td>31.9%</td><td>34.8%</td><td>1.8%</td><td>5.2%</td></tr>
<tr><td>55-64</td><td>34.4%</td><td>33.2%</td><td>2.6%</td><td>4.9%</td></tr>
<tr><td>65-74</td><td>38.2%</td><td>34.0%</td><td>2.7%</td><td>3.3%</td></tr>
<tr><td>75-95</td><td>23.5%</td><td>28.0%</td><td>1.6%</td><td>1.9%</td></tr>
</table>

This data shows correlation between obesity and aging, until later life.
</td></tr>
<tr><td>Disability: physical, sensory, and learning impairment; mental health condition; long-term conditions</td><td>Compared to those with no self-reported disabilities, the prevalence of excess weight is 11% higher amongst those self-reporting any long-term physical and mental health conditions or illnesses that have a substantial effect on their ability to carry out normal daily activities.[1]

The phasing scenario whereby those with multiple comorbidities are proposed to receive the drug sooner than those with fewer would align to supporting those with disabilities – specifically long-term conditions – to access the drug soonest and with the least delay.

Using a phasing approach where priority is given to those with more weight related comorbidities would support access and equalities considerations.</td></tr>
<tr><td>Race and ethnicity[2]</td><td>The prevalence of obesity varies by ethnicity. Black adults have the highest rate of overweight and obesity, while Chinese adults have the lowest.

Public Health Outcomes Framework 2020/21 data, Office for Health Improvement and Disparities, published March 2023.
<table>
<tr><th>Ethnicity</th><th>%</th></tr>
<tr><td>All</td><td>63.5</td></tr>
<tr><td>Asian</td><td>57</td></tr>
<tr><td>Black</td><td>72</td></tr>
<tr><td>Chinese</td><td>37.5</td></tr>
<tr><td>Mixed</td><td>59.5</td></tr>
<tr><td>White British</td><td>64.5</td></tr>
<tr><td>White other</td><td>57.9</td></tr>
<tr><td>Other</td><td>66.2</td></tr>
</table>
</td></tr>
</table>

[1] PHE Fingertips – Public Health Outcomes Framework. Available from: https://fingertips.phe.org.uk/profile/public-health-outcomes-framework

[2] Addressing racial inequalities is about identifying any ethnic group that experiences inequalities. Race and ethnicity include people from any ethnic group incl. BME communities, non-English speakers, Gypsies, Roma and Travelers, migrants etc. who experience inequalities so includes addressing the needs of BME communities but is not limited to addressing their needs, it is equally important to recognise the needs of White groups that experience inequalities. The Equality Act 2010 also prohibits discrimination on the basis of nationality and ethnic or national origins, issues related to national origin and nationality.

	The NICE recommendation for tirzepatide accommodates the lower BMI clinical threshold for people from South Asian, Chinese, other Asian, Middle Eastern, Black African or African-Caribbean ethnic backgrounds. As the NICE recommendation makes this ethnically related clinical adjustment, so does our Alternative Implementation Proposal (IP). In-keeping with the NICE recommendation, to support fair clinical prioritisation and to ensure equitable access across ethnicities, NHSE proposes adjusting down the BMI thresholds of each cohort by 2.5kg/m^2 for the relevant groups of patients. As a result, we believe the IP mitigates any ethnicity bias in the clinical prioritisation that creates our cohorts.
Sex: men; women	Overall, 67% of men and 62% of women were classed as overweight or obese. Being overweight was more common in men, but obesity was more common in women and this is reflected in admissions directly attributable to obesity, where 74% of patients were female in 2017/18[3]. Inequalities also exist in accessing services. Weight management services (behavioural interventions and bariatric surgery) are more frequently accessed by women, and early finds from the National Diabetes Prevention Programme show men are more likely to drop out of weight management services[4]. Gender split. Men – 25% Women – 26% (Obesity Statistics, House of Commons Library, January 2023)
People or families on a low income	The impact of phasing on low-income households has been considered. The income of the household should not determine access to the medicine, and obesity is associated with social and economic deprivation across all age ranges and is becoming increasingly common. For adults, the prevalence of excess weight was 11% higher in the most deprived areas compared with the least deprived[5]. However, in this instance, there are two possibilities regarding access to this medicine. 1) That those with greater wealth are able to access the drug through private prescriptions, if motivated to.

[3] NHS Digital (2019) Statistics on Obesity, Physical Activity and Diet, England, 2019
[4] Valabhji J, Barron E, Bradley D et al. (2020) Early Outcomes From the English National Health Service Diabetes Prevention Programme. Diabetes Care. Vol 43(1): 152-160. https://doi.org/10.2337/dc19-1425
[5] PHE Fingertips – Public Health Outcomes Framework. Available from: https://fingertips.phe.org.uk/profile/public-health-outcomes-framework

	2) That those with wealth and drive are able to qualify for access to the drug in a more open implementation programme, on account of their motivation to receive it. On 1), there is a risk that phasing implementation encourages lower clinical priority individuals to seek the medicine outside of the NHS, self-funding the treatment. Eli Lilly has reassured NHSE that there will be sufficient supply to treat NHS patients for obesity management in the near and short term and we do not consider the private market to be a high risk to medicines supply for NHS patients. However, this risk is also active under the 90-day implementation scenario, whereby those who cannot access a GP appointment for review due to either capacity constraints or local prioritisation processes seek a prescription in the private sector. Arguably the risk is higher in this scenario, as general patient knowledge and public awareness of the treatment would be higher, with expectations raised, if patients expect broad access to the medicine 90-days after FAD. On 2), we assume a link between income and motivation to gain treatment access. However, it remains true that broad implementation would create a major displacement of GP appointment capacity that would have a highly damaging impact on wider population access to GP services Those better able to navigate the system and gain within a more restricted capacity environment are unlikely to reflect clinical priorities.
People living in deprived areas	NHSE considers that there is a higher likelihood of geographically equitable access between and within ICBs if there is a centrally designed implementation plan based on phased clinical need. This plan will provide a framework for implementation based on a recommended approach, including manageable patient cohorts. Under this approach, those who live in all parts of England stand a better chance of gaining early access to the treatment, if they meet the threshold of clinical need. Under a 90-day implementation approach, we could reasonably assume that there will be a small number of commissioners prepared to offer this medicine and it is patients in those areas who would access the medicine early. This risks that lower clinical priority patients in one geography would gain access before higher priority patients in another. This is due to both the availability of services to support medicine use and to demands on the medicine supply. However, by limiting NHS availability to those with the highest clinical priority in the first instance, we accept that those with financial means may be able to circumnavigate this clinical prioritization and access the treatment through the private market, gaining access prior to their clinical prioritisation cohort. However as previously explained, we believe it is a false dichotomy to assume that introduction without a FV would allow widespread adoption. We believe the choice is between a managed introduction via the FV and a sclerotic introduction based on local commissioning priorities and provider willingness. In a standard implementation environment, we may also assume that those with the means to access

	the treatment privately may also have the wherewithal to access the treatment early through the NHS. To support a consistent level of access to patients in all geographies, including those living in deprived areas, a phased approach with a threshold based on clinical need offers the best option.
Other groups experiencing health inequalities (please describe)	Other subgroups who may require access to the medicine include those in care homes, and those in the justice system. A centrally coordinated phased roll out will also avoid disadvantaging those in these settings beyond any variation in treatment and services they already experience. For care homes, these come under the remit of primary care services and so access would be equitable to other patients (withstanding the issues raised above concerning motivated patients and those who can navigate the system to gain access). Patients in care homes may be least likely to elect to request the medicine but equally likely to benefit from it. Regarding **health services in the justice system**, there is need to commission a new treatment pathway for this patient group, equivalent to that provided to the general population. This will be required for those in the justice system to be initiated onto treatment and to allow for the transition of care back and forth from NHS services as patients move in or out of secure facilities (to avoid unwarranted drop-off transferring between settings). **Mental Health** While obesity rates among the general population are increasing, for those with severe mental illness (SMI), the rate is even higher due to a combination of factors, including, poor diet, alcohol use, the effect of medications to manage effects of mental ill health and less active lifestyles. Recent GP data suggests that obesity rates are almost double in patients living with SMI compared to all patients[6]. In addition, people with severe mental illness have a low take-up of information and interventions relating to obesity.
NHSE does not believe that the FV will result in any specific additional negative health effects on the following groups: • Gender Reassignment and/or people who identify as transgender • Marriage and Civil Partnership • Pregnancy and Maternity • Religion and belief • Sexual orientation • Carers • Homeless people • People involved in the criminal justice system • People with addictions and/or substance misuse issues • People with poor literacy or health literacy • People living in remote, rural and island locations • Refugees, asylum seekers or those experiencing modern slavery.	

[6] PHE (2018) Severe mental illness (SMI) and physical health inequalities: briefing

Considering the above, and the contextual information provided in this FV request, NHSE contends that the Alternative Implementation Proposal (IP) made in this FV is cognisant of health inequalities issues and is designed in such a way as to reduce health inequalities related to obesity and overweight.

If the TA is implemented without a FV, we believe there is a risk that those with the greatest clinical need may be lost within the high immediate demand this drug's availability will create. Similarly, there will be geographic inequalities based on the different approaches taken by commissioners in different parts of the country, including different levels of commitment, and ability to implement, the TA recommendation.

The NHSE IP offers the best chance of consistent and equitable access to NHS treatment given that obesity is not a geographically concentrated condition.

This, combined with the proposed supportive NHSE funding approach of providing dedicated new funding to all ICB commissioners, along with an offer of central reimbursement for medicine costs plus a contribution to service costs based on forecast eligible population (subject to a successful Spending Review funding request), means that barriers to introducing a tirzepatide pathway in all areas of England are lowered.

The approach is blind to all considerations other than clinical need.

NHSE considers that the risk of a supply shortage of this medicine is greatest in its initial years of use. In the event of a supply shortfall, the clinical prioritisation approach would ensure that any supply is first and foremost directed towards those patients with the greatest clinical need.