Medical Card Eligibility for People with Cystic Fibrosis



Cystic Fibrosis Ireland

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Introduction

This paper addresses the need for the medical card to be automatically made available to all **People with Cystic Fibrosis (PWCF)**. It highlights the many important benefits of the medical card which are currently not made available to all PWCF because of income thresholds, and reinforces the importance of the Long-term illness (LTI) scheme for PWCF.

People with certain conditions can get free drugs, medicines and medical and surgical appliances for the treatment of that condition under the LTI scheme. Cystic Fibrosis (CF) is an illness that is recognised as one of the qualifying medical conditions under this scheme.

PWCF can also apply for the medical card or GP visit card; however, access to these supports is means tested. Some PWCF have access to the medical card because they are below income thresholds but also some PWCF are able to access the medical card on discretionary grounds because of the nature of the illness. There appears to be widespread inconsistencies in the awarding of medical cards on a discretionary basis.

Furthermore, the process whereby medical cards are reviewed for existing medical card holders (which generally occur on an annual basis) causes considerable anxiety and questions asked are sometimes inappropriate and portray a lack of understanding about CF, which is a chronic, life shortening, long-term illness. As one PWCF noted: *"It's very upsetting to have to go through all that especially when they ask you 'how long do you expect the condition to last?'"* and "*having to continue proving you have a terminal illness is quite bizarre".* It is unreasonable to ask a person with an incurable progressive illness to prove that they still have the condition on an annual basis.

The medical card provides additional vital support to PWCF who experience secondary complications as a result of CF. With increasing age and more advanced lung disease, PWCF are now confronted with a myriad of potential secondary complications including, osteopenia/osteoporosis, diabetes, liver disease, asthma, nasal polyps, pneumothorax and haemoptysis[1] – all of which require complex medications and treatments. Additional and ongoing secondary complications also include sinus care/treatment, gastroesophageal reflux disease (GORD), which affects approximately 30% PWCF, constipation and distal intestinal obstruction syndrome (DIOS)[2].

[1] Cystic Fibrosis Registry of Ireland Annual Report 2012
[2] European Cystic Fibrosis Society Standards of Care: Best Practice guidelines, Journal of Cystic Fibrosis 13 (2014) S23–S42

We are concerned that the expert panel charged with examining how medical needs should be taken into account in the context of medical card eligibility is predominantly led by clinical experts. The views of patients are central to the process since they provide a user perspective; we urge further engagement with patient/advocacy organisations, or with an umbrella body (such as Disability Federation of Ireland) before the expert panel proceed any further.

We contend that, based on medical need, all PWCF be automatically and permanently granted the medical card, or that an alternative mechanism is established to ensure that all the supports currently provided under the medical card are made available to those on the LTI scheme.

We call on government to implement the legal and legislative measures required to provide medical card eligibility on the basis of medical need, and for people with CF to be included in this cohort based on their lifelong progressive illness.

What is Cystic Fibrosis?

Ireland has the highest incidence of Cystic Fibrosis in the world with almost 7 in every 10,000 people with the disease. The incidence of Cystic Fibrosis in Ireland is almost three times the average rate in other EU countries and the United States[3]. According to the latest annual report from the Cystic Fibrosis Registry of Ireland (CFRI) in 2012, there are 1,140 individuals with CF living in Ireland – over half of CFRI-registered PWCF were aged 18 years or older (52.2%), and the adult population continues to increase on an annual basis[4]. The median age of death in Ireland is 25 years of age, though those born in later years can expect to live into their 30's and beyond. There is no cure for CF.

Cystic fibrosis is caused by alterations in the cystic fibrosis transmembrane conductance regulator (CFTR) protein[5], which affects the regulation of absorption and secretion of salt and water in various parts of the body, including the lungs, sweat glands, pancreas, and gastrointestinal tracts. In people without CF, the CFTR protein controls the flow of salt and water through the body's cells, keeping mucus on the inside of the body's organs thin and watery. PWCF account for some of the heaviest and most consistent users of the health system in Ireland as a result of ongoing routine and annual assessments, and inpatient admissions due to exacerbations.

PWCF produce large volumes of thick, sticky mucus, which can clog airways and harbour harmful bacteria. Symptoms reported by PWCF vary significantly in severity, from very mild to debilitating. The most common symptom associated with CF is recurrent chest infection, which results in lung damage, with the majority of death's occurring through respiratory failure[6]. Other medical issues associated with CF include; CF-related diabetes, osteoporosis, malnutrition, liver disease and infertility, particularly in males. Since CF attacks so many body parts at once – respiratory, digestive and reproductive – a specialised, multi-disciplinary team of healthcare professionals is essential for the care of patients. This multi-disciplinary team generally consists of a CF Specialist Consultant, a CF Specialist Nurse, a Physiotherapist, a Dietitian, a Psychologist, a Social worker, a Microbiologist, and a Pharmacist.

There has been a steady increase in the number of adults living with CF thanks to improved care in recent years. However, with this increased life expectancy, and the rising numbers of PWCF undergoing transplant, come other secondary complications, which the Irish health service must respond to.

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[3] Farrell PM. Journal of Cystic Fibrosis 2008 Sep: 7 (5) 450-453 which revealed a mean prevalence of 0.737/10,000 in the 27 EU countries which is similar to the value of 0.797 in the United States and only one outlier, namely the Republic of Ireland at 2.98/10,000 population. Recently revised to three times the average in the US and the EU.

[4] Cystic Fibrosis Registry of Ireland Annual Report 2012

[5] Ramsey, B. W., J. Davies, et al. (2011). "A CFTR Potentiator in Patients with Cystic Fibrosis and the G551D Mutation." *New England Journal of Medicine* 365(18): 1663-1672.

[6] Cystic Fibrosis Registry of Ireland Annual Report 2012

An Ageing CF Population with Changing Needs

The outlook for PWCF has improved greatly since the inception of the LTI scheme in 1970. Cystic fibrosis is no longer regarded as a paediatric condition. Adults with cystic fibrosis are now working, travelling and having families of their own. The latest annual report from the Cystic Fibrosis Registry of Ireland reveals that the adult population continues to increase on an annual basis and over half of CFRI registered members are now aged 18 years or older (52.2%)[7].

With their increasing age and more advanced lung disease, several important sequelae (both pulmonary and extrapulmonary) occur in these adult patients including pulmonary disease, cystic fibrosis-related diabetes, renal disease, metabolic bone disease, cancers, drug allergies and toxic effects, and complications associated with lung transplantation.[8]

Other ongoing secondary complications PWCF experience include gastroesophageal reflux disease (GORD), which affects approximately 30% PWCF, constipation and distal intestinal obstruction syndrome (DIOS)[9] – the drugs for treating such complications are often 'over the counter' and are not covered on the medical card or LTI (e.g., gaviscon, kleen prep). The expense incurred as a result of such secondary complications accumulates when such medications form part of a person's daily treatment regime.

Over time PWCF accumulate significant damage and scar tissue in the lungs, which causes a steady decline in the patient's lung function – leading to end-stage lung disease. Lung transplantation is the most aggressive therapy available for end-stage lung disease, in which conventional medical treatment has little to offer.

Lung transplantation rates for PWCF in Ireland are on the rise; there were a total of 4 lung transplants for PWCF in 2012 and this more than doubled to 9 in 2013.[10] As of 25th June there have already been 11 CF double lung transplants in Ireland in 2014. With the recent commitment from the government of €2.9m for a new transplant programme in the Mater Hospital in Dublin, we can now be hopeful that these numbers will continue to rise.

See **Annex 1** for more information about supports for PWCF post-transplant.

[7] Cystic Fibrosis Registry of Ireland Annual Report 2012
[8] Management of comorbidities in older patients with cystic fibrosis. Plant BJ, Goss CH, Plant WD, Bell SC. Lancet Respir Med. 2013 Apr;1(2):164-74.
[9] European Cystic Fibrosis Society Standards of Care: Best Practice guidelines, Journal of Cystic Fibrosis 13 (2014) S23–S42
[10] CFI Impact & Annual Report 2012/3

Employment and the Medical Card

The medical card should be issued permanently to PWCF to enable them to plan for their future without fear or anxiety that the necessary supports could be withdrawn depending on their personal circumstances (e.g., employment/marital status).

Engaging in employment is actively encouraged by CFI to promote independence and facilitate full participation of members in society. However, due to the unpredictable nature of CF, an exacerbation can happen at any time – as a result many PWCF are reluctant to go down this road for fear of losing crucial benefits, such as the medical card, which could be very difficult to get back. The present system of issuing medical cards based on income thresholds limits the opportunity for PWCF to seek employment, it is in fact disabling.

It is imperative that the medical card is made available to PWCF irrespective of employment status to eliminate the anxiety over critical supports being taken away and to enable them to (re)enter the workforce and live independently.

Current Supports for People with CF

Under the current health system PWCF access most of their medications through one of two means: the LTI scheme and/or the medical card. It is of utmost importance that PWCF continue to receive all medications which are essential to the treatment of CF through these schemes.

Long-Term Illness Scheme

Cystic Fibrosis is a long-term illness that is recognised under the LTI scheme. The LTI scheme does not depend on income or other circumstances (e.g., employment or marital status) and is separate from the medical card scheme and the GP visit card scheme. PWCF are automatically allowed an LTI book. The LTI book lists the drugs and medicines for the treatment of CF, which are provided for free through the community pharmacist. In a similar manner, we believe that CF should be an illness automatically recognised for inclusion under the medical card scheme.

Medical Card

The medical card in contrast is means tested, other than discretionary cards provided on exceptional need. To qualify for a medical card, weekly income must be below a certain figure for a family size/individual. Cash income, savings, investments and property (except for your own home) are taken into account in the means test. PWCF are not automatically entitled to a medical card. Medical cards allow people to access family doctor or GP services, community health services, dental services, prescription medicine costs, hospital care and a range of other benefits free of charge – all of which provide a vital role in the care of a PWCF.

A prescription charge of €2.50 per item is associated with the dispensing of medications under the medical card scheme, up to a maximum of €25 per month per person or family.

Note: A change in Department of Health policy in the last quarter of 2013 meant that those eligible for the LTI scheme could also hold a medical card providing they met the required criteria. This was welcomed amongst members since there are no prescription charges associated with the dispensing of medications through the LTI scheme.

Hi-Tech Drug Scheme

Over the past year new therapies which significantly improve the quality of life and clinical outcomes for PWCF have been approved for use by the European Medicines Agency (EMA). These new therapies fall under the category of ‘personalised medication’, and are extremely expensive. Many essential and routine CF medications, including anti-rejection drugs for transplant patients, are administered through the High-Tech Drug scheme.

Other schemes PWCF can avail of include the Drug Payment Scheme and the Hardship Scheme.

The various schemes catering for PWCF (medical card, LTI, Hardship, Hi-Tech Drug scheme) appear to be causing confusion amongst members. None of these schemes cater for **all** CF medications. For example, some medications are not available through the medical card, such as vitamins and hypertonic sodium chloride solution – both of which are evidence based approaches for the treatment of CF.[11]

Note: There are several 'over the counter' treatments that form an integral part of the routine care and treatment for a PWCF, which are not covered on the LTI or medical card. For example, sinus care treatment requires items such as sinutab, sudafed and sinus rinses as a result of bacterial colonisation of the sinus. In addition, gaviscon and kleen prep are also required for symptom relief and/or treatment of gastrointestinal complications, which are very common amongst PWCF. The ongoing expense of purchasing such medications that form an essential part of the treatment regime of a PWCF results in a growing economic burden on our members.

Members have expressed the desire to have a single scheme, such as the medical card, that covers all their CF-specific and secondary-related medications and supports. While exploring all options to increase accessibility to these services, we seek assurances that existing services are not diluted in an effort towards making necessary improvements.

[11] European Cystic Fibrosis Society Standards of Care: Best Practice guidelines, Journal of Cystic Fibrosis 13 (2014) S23–S42

The Benefits of the Medical Card

There are many benefits and supports that are currently available through the Medical Card, which are not available through the LTI scheme. As all PWCF are not currently automatically granted the Medical Card based on medical need, there is a large portion of our membership that are not getting access to a cohort of additional services, which are outlined below. These services provide security to PWCF that their lifelong healthcare requirements will be met.

Free Access to GP

Medical Card holders have free access to their GPs. PWCF on the LTI scheme must pay the full consultation fee, which can vary from €30 to €70 per visit. The GP provides a vital resource to PWCF in taking bloods to assess toxicity levels when on intravenous antibiotics, monitor sugar levels for Cystic Fibrosis Related Diabetes (CFRD) and other vitamin deficiencies that may occur in PWCF.

Having blood tests taken locally relieves pressure from the CF centres and reduces travel for the PWCF. The GP is also the gateway for required medical certificates, e.g., for application for social welfare payments and for absence from work, which is often common amongst adults with CF engaged in employment. The flu vaccine is also administered through the GP, and this is critical for all people with CF on an annual basis.

A recent survey carried out by CFI (n= 259)[12], revealed that a large proportion of families affected by Cystic Fibrosis depend on their local GPs for support and advice. Just over 58% of parents report bringing their children to the local GP 1-4 times in the last year. Some 25% attended the GP 5-10 times, and 11.5% didn't go at all. A lower rate of 3% of respondents went 11-15 times.

Over 50% of members reported that the cost associated with visiting the GP is a barrier to accessing the necessary advice and support, for those who do not have a medical card or GP visit card. As mentioned by one parent *"The cost of GP visits are so expensive – it would give us the peace of mind to go to doctor whenever we are worried about something".*

The high cost of GP visits are acting as a disincentive for those who do not have a medical card/GP visit card to go to their local GP. Rather than checking in with the GP if they are

[12] Medications and Health Service Supports for PWCF and Parents, CFI Survey, December 2013

worried about something, they will postpone it for as long as possible to avoid the potential cost, which could have serious repercussions resulting in exacerbation and/or hospital admission.

Most parents link in directly to the CF centre for advice and support in relation to CF since the multidisciplinary team are the experts in CF; however, many parents and PWCF reported depending quite a lot on their local GPs, especially where they live a considerable distance from the specialist CF centre, and where the GP has an interest in the condition. The option of visiting the GP is also preferable to being admitted to a CF centre through A&E where the risk of cross-infection would be considerably higher.

Free access to GP services is a significant benefit of the medical card compared with the LTI scheme, and we strongly support its availability for PWCF based on medical grounds.

Waiver of Inpatient Charges

People who hold a medical card are not liable for hospital inpatient charges. People who **do not** hold a medical card can be liable for inpatient charges of €75 per day up to a maximum of €750 in any 12 consecutive months.

Each year, greater numbers of hospitalisations, respiratory exacerbations requiring IV antibiotics and complications, are recorded for PWCF by the CFRI[13]. Given that each hospital admissions for a PWCF would generally last 1-2 weeks, it is likely that most PWCF who do not hold a medical card are liable for the maximum inpatient charge.

The potential cost of hospital inpatient charges for those not holding a medical card creates a lot of anxiety for PWCF and their families who may not be in a position to meet such costs. This acts as a disincentive in PWCF seeking treatment as an inpatient – the resultant postponement in admission could lead to further exacerbation of infection and longer inpatient care, which is more costly in the long term. Note that A&E charges do not apply for those who hold a medical card.

CFI seek assurances from government that PWCF who do not hold a medical card are not liable for inpatient charges as a result of a hospital admission relating to CF or CF-related complications.

[13] Cystic Fibrosis Registry of Ireland Annual Report 2012

Support for Secondary Complications Related to CF

The medical card provides additional support to PWCF who experience secondary complications as a result of CF. With increasing age and more advanced lung disease, PWCF are now confronted with a myriad of potential secondary complications including, osteopenia/osteoporosis, diabetes, liver disease, asthma, nasal polyps, pneumothorax and haemoptysis[3] – all of which require additional and complex medications and treatments. Other complications, which are ongoing for many PWCF, include GORD, constipation, DIOS and sinus care/treatment (for PWCF with upper respiratory symptoms as a result of bacterial colonisation in the sinus).

All medications and health service supports should be made available to PWCF who experience secondary complications as result of CF.

Auxiliary Services and Supports

Certain Dental, Ophthalmic (Eye), and Aural (Ear) health services are provided for free to medical card holders, which are not available to those on the LTI scheme.

These services and supports are particularly important for PWCF on the active transplant list and post transplant, as post-transplant drugs can have a significant impact on eyes and ears[14]. Medication and diet could be considered as a risk factor for dental caries in PWCF[15].

The treatment of CF lung disease can result in complications due to the treatment and toxicity related to medications, especially aminoglycosides (e.g. nephro-, oto-, and vestibular toxicity)[16] – full access to the necessary specialities to treat such complications is essential.

These auxiliary services should be made available to all PWCF directly though the medical card or as an adjunct to the LTI scheme.

Medical & Midwifery Care for Mothers

This includes health care related to pregnancy and the care of the child for six weeks after birth.

[14] Lung transplant patient information booklet, the Mater hospital (2006): www.mater.ie/media/media,9141,en.pdf

[15] Related factors of dental caries and molar incisor hypomineralisation in a group of children with cystic fibrosis. Peker S1, Mete S, Gokdemir Y, Karadag B, Kargul B. Eur Arch Paediatr Dent. 2014 Feb 26.

[16] European Cystic Fibrosis Society Standards of Care: Best Practice guidelines, Journal of Cystic Fibrosis 13 (2014) S23–S42

Personal and Social Care Services

For example:

a. Public health nursing (can facilitate access to home help, personal assistant services)
b. Social work services
c. Other community care services (in particular home physiotherapy* See **Annex 2**)

Additional benefits if you have a Medical Card

The following benefits may also be available for medical card holders:

- No need to pay the health portion of your social insurance (PRSI);
- Free transport to school for children who live 3 miles or more from the nearest school;
- Exemption from state examination fees in public second-level schools;
- Financial help with buying school books. The benefits above are available from the relevant government department.

Assisted Fertility Treatment

Approximately 98% of males with cystic fibrosis are infertile[17]. This is normally due to absence of the vas deferens, a tube that carries sperm from the testis to the penis – in males with CF this tube fails to develop properly and may prevent the passage of sperm to their intended destination. Fertility problems in females with CF may be related to general ill health, poor weight, or poor control of CF-related diabetes mellitus.

A number of fertility clinics in Ireland currently offer reduced rates of assisted fertility treatment (e.g., IVF, ICSI) to people with CF who are both medical card holders. As these procedures are extremely costly, the medical card is very helpful in this respect.

We contend that all of the above benefits, which are not available through the LTI scheme, be automatically made available to all PWCF irrespective of income, but based on medical need. All PWCF are born with this genetically inherited, progressive, lifelong condition and should be afforded with all of the necessary supports listed above as a matter of priority.

[17] Fertility in Men With Cystic Fibrosis*: An Update on Current Surgical Practices and Outcomes, McCallum et al 2000. Chest. 2000;118(4):1059-1062

Medical Card Reviews

Members' experiences of the medical card review process were investigated by CFI in a recent survey.[18] The survey revealed that many members found this process to be "*Very, very stressful and time consuming."*

Parents have reported the convoluted application processes to be *'both upsetting and demeaning'*. We would ask the Department to be cognisant of these issues in order to allow families to access the relevant supports in a way that will not cause further undue anxiety and stress.

There also appears to be some disparity in the length of time medical cards are validated for. For example, some people have been issued it for one year, others 2, and some even 5. The reapplication process is noted as causing a high degree of stress and anxiety for parents – *"It's very upsetting to have to go through all that especially when they ask you 'how long you expect the condition to last?'"* and "*having to continue proving you have a terminal illness is quite bizarre".*

Several parents reported that the existing medical card became invalid during the lengthy review process. As a result the family were asked to pay for medications since no provisional supports were put in place to account for such lengthy periods of review. This places an unfair burden on families who are already struggling financially.

"The process takes a long time and I'm afraid I won't receive the new card before the old card has expired. A very stressful event"

As Cystic Fibrosis is a genetically inherited, life-long disease and is progressive by nature, we would argue that the medical card should be automatically granted to PWCF and no further assessments or follow-up reviews should be required to assess their eligibility to this scheme.

[18] Survey on 'CFI Medications and Health Service Supports', December 2013

Actions and Recommendations

Cystic Fibrosis is a genetically inherited, lifelong illness that is progressive in nature – this must be acknowledged in considering eligibility for the medical card. There appears to be a lack of appreciation of the cause, prognosis and treatment of people with CF among some of those that make decisions about medical card eligibility.

The outlook for PWCF has improved greatly in recent years. Cystic fibrosis is no longer regarded as a childhood disease and adults with cystic fibrosis are now working, travelling and having families of their own.

However, with their increasing age and more advanced lung disease, several important sequelae (both pulmonary and extrapulmonary) occur in these adult patients including pulmonary disease, cystic fibrosis-related diabetes, renal disease, metabolic bone disease, cancers, drug allergies and toxic effects, and complications associated with lung transplantation.[19] Treatments for all CF-related secondary complications must be recognised and covered under a single scheme for all PWCF.

The LTI scheme is an invaluable resource for members to receive vital medications; however, it does not encompass the many auxiliary supports that are available through the medical card scheme. We contend that **people with Cystic Fibrosis should be automatically granted the medical card following diagnosis** as part of the newborn screening programme and no further assessments should be required to ascertain eligibility to this scheme.

In conclusion:

- CFI calls on medical cards to be issued **permanently** to all people with Cystic Fibrosis based on the fact that they live with a genetically inherited, progressive, lifelong condition – this would assure our members that if their circumstances should change, their medications, treatments and basic healthcare needs are met for the future.

- Treatments for all CF-related secondary complications must be recognised and covered under a single scheme for all PWCF.

- Free access to GP services is a significant benefit of the medical card compared with the LTI scheme, and we strongly support it's availability for PWCF based on medical grounds. Access to the GP may also keep PWCF out of hospital for longer.

[19] Management of comorbidities in older patients with cystic fibrosis. Plant BJ, Goss CH, Plant WD, Bell SC. Lancet Respir Med. 2013 Apr;1(2):164-74.

- CFI seek assurances from government that PWCF are not liable for inpatient charges as a result of a hospital admission relating to CF or CF-related complications.
- We call on government to implement the legal and legislative measures required to provide **permanent** medical card eligibility on the basis of medical need, and for people with CF to be included in this cohort based on their lifelong progressive illness.
- We suggest that the medical card be issued to all PWCF as an adjunct to the existing LTI Scheme, or that an alternative mechanism be established to make all complementary supports available to those on the LTI scheme.
- Existing services must not be diluted in an effort towards making necessary improvements.
- CFI calls for a seat on the expert panel which has been charged with recommending the medical conditions that should be considered when determining medical card eligibility

Annex 1: Support for People with CF Post-Transplant

Over time PWCF accumulate significant damage and scar tissue in the lungs, which causes a steady decline in the patient's lung function – leading to end-stage lung disease. Lung transplantation is the most aggressive therapy available for end-stage lung disease, in which conventional medical treatment has little to offer. Cystic Fibrosis is the main illness resulting in double lung transplantation in children over 5 years of age and the third most common illness resulting in double lung transplantation in adults, as reported by the registry of the International Society for heart and lung transplantation[20].

Lung transplantation is not an option for all PWCF with end-stage pulmonary disease, with many variables being taken into consideration such as; lung, heart and kidney function, bacteria growing in the lungs, psychological and social well-being.

The government have committed €2.9m for a new transplant programme in the Mater Hospital in Dublin recently with 19 new transplant and organ donation staff including organ donor co-ordinators.

Lung transplantation rates for PWCF in Ireland are on the rise; there were a total of 4 lung transplants for PWCF in 2012 and this more than doubled to 9 in 2013.[21] As of 25th June there have already been 11 CF double lung transplants in Ireland in 2014. With the recent commitment from the government, we can now be hopeful that these numbers will continue to rise.

[20] P. Aurora, L.B. Edwards, J.D. Christie et al. (2009). Registry of the International Society for Heart and Lung Transplantation: Twelfth Official Pediatric Lung and Heart/Lung Transplantation Report—2009
J Heart Lung Transplant, 28, pp. 1023–1030

[21] CFI Impact & Annual Report 2012/3

Annex 2: Physiotherapy Costs

The number of daily physiotherapy sessions is generally two, but this can increase during times of infection to three or even four. As one member commented *'To put it bluntly, a physiotherapist charges an average of €50 per half hour session. We carry out 14 sessions weekly (64 per month), which would cost €3,200 per month, just for this one task that we must complete every day. By not carrying out this task we are putting our child's life in danger and ensuring that he would have to stay in hospital for extended stays, costing the state much more.'*