



FLORIDA SOCIETY OF CLINICAL ONCOLOGY
SPECIAL FLASCO BLAST –November 17, 2009
FLASCO WEBSITE: www.flasco.org
FLASCO CLINICAL TRIALS NETWORK WEBSITE: www.fctn.org

BOARD OF DIRECTOR ACTIONS – NOVEMBER 6, 2009

LCDs

The process for creating and revising LCDs in the new MAC Jurisdiction has changed. It is causing a considerable amount of work for FLASCO members who take the responsibility for working with First Coast Service Options in this regard. Dr. Robert Cassell volunteered to be the designated representative of FLASCO to send request and required documentation to FCSO on all future new or revised LCDs.

ACTION: Dr. Robbins, as President of FLASCO, is going to write another letter to the Florida Medicare Medical Director regarding this issue and will request that face to face meetings be reconsidered. FLASCO only wants to meet face to face with the policy employees, not the educational team, etc. Perhaps let FLASCO sponsor a meeting in an attempt to redefine the process.

CLINICAL PRACTICE ACTIONS:

1. A motion was made, second and carried for Dr. Robbins to write a cover letter and that the Position Statement be distributed to all identified Private Payor Medical Directors. The position statement also to be distributed to all FLASCO Members and Corporate Members. (Position Statement attached to this Fax Blast)
2. Dr. Marsland has had some previous dialogue with Dr. Cook from Cigna; therefore, he will try to set up a face to face meeting with him.
3. An attempt will be made to identify other Private Payer Medical Directors and Dr. Marsland will attempt to set up face to face meetings with these Medical Directors and their company.
4. It was agreed that Dr. Marsland have a professional review and re-write, if needed, the Position Statement and then he should attempt to have it published in as many journals as possible.

LEGISLATIVE:

1. State Sen. Don Gaetz, chairman of the Senate Committee on Health Regulation, (R-Niceville, FL), the Florida Medical Association (FMA), the American Cancer Society of Florida, Dr. Michael Good, interim dean of the University of Florida College of Medicine, Deputy Insurance Commissioner Mary Beth Senkewicz, the Leukemia & Lymphoma Society and many others continue to meet with insurers to strongly encourage them to cover services involved with clinical trials. Sen. Gaetz and his team continue to send a clear message to insurers that a legislative solution may be pursued if needed. **Action for FLASCO:** Watch and be ready to support the FMA and other associations as needed. Also, Dr. Dunbar to attempt to secure an appointment with Senator Gaetz for her and Dr. Robbins to meet with him. Also to work through the FMA. Let the Senator know that FLASCO is willing to work with him – invite him to one of our future meetings.

2. It was agreed that FLASCO would support HR 1740 – To amend the Public Health Service Act to increase awareness of the risks of breast cancer in young women and provide support for young women diagnosed with breast cancer. *as introduced.*– Congresswoman Debbie Wasserman Schultz
3. Need to continue to monitor the rule making regarding licensing renewal and felonies.
4. Every FLASCO member should let the FLASCO office know if they have a personal relationship with a State or Federal Legislator – need to foster these relationships.

2010 FLASCO PROGRAMS

The 2010 Annual Meeting and Spring Session will be held at the Tampa Airport Marriott Hotel on March 5-6, 2010.

The 2010 Fall Session will be held in Miami on November 5 -6, 2010.

The 2010 PA/NP Conference will be held at the Miami Heart Institute on March 26, 2010 – Brenda Pate, PA-C gave an update on this Conference.

ACTION: It was voted for FLASCO to develop and implement a Florida Oncology University for pharma and bio tech representatives. It will be held in Tampa on Thursday, April 8, 2010. Dr. Thomas Marsland was appointed chairman of the committee to plan this initiative.

The 2nd Annual Business of Oncology Summit will be held on October 2, 2010 in either Tampa or Orlando. It will be a statewide Summit and consideration will be given to inviting participants from other States.

AD HOC COMMITTEE APPOINTMENTS:

Business of Oncology Conference:

Richard Levine, MD, Chairman
 Alan Collin, MD
 Phillip Dunn, MD
 Michelle Smith Flowers
 Lucio Gordan, MD
 Thomas Niederman, MD

Conference for Pharma and Bio Tech:

Thomas Marsland, MD, Chairman
 Robert Cassell, MD
 Leonard Kalman, MD
 Jeff Panoessa, MD
 William Harwin, MD
 Robert Green, MD

Fellows Programs

Gerardo Colon-Otero, MD, Chairman
 Robert Cassell, MD
 Medhi Moezi, MD
 Randal Henderson, MD

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FLORIDA SOCIETY OF CLINICAL ONCOLOGY POSITION PAPER (Draft)

The cost of health care today is a major issue at the top of the discussions at many levels. It is clear to every one that the cost of care is rising at an unsustainable rate. The United States spends 16% of its gross domestic product on health care. This amounts to more than 2 trillion dollars in expenditures. Numerous studies show that the growth in health care is exceeding the growth in the overall economy.

At current trends, health care expenditures are expected to reach 20% of the gross national product by 2017. The cost of cancer care contributes significantly to these projections. The NIH estimates that 89 billion dollars was spent on cancer care in 2007. Over 19 billion of this was spent directly on drugs (**ref. #1**).

There are a number of factors that contribute to this rapid expansion in expenditures on cancer care. One is the rising incidence of cancer within the United States as our population ages. Although it is encouraging that cancer patients are now living longer, this also helps to explain the rising cancer expenditures. Each patient is now consuming a greater share of cancer dollars due to their increasing life expectancy.

The final factor in the rising cost of cancer treatments is the introduction of newer treatments and technologies. Newer technologies such as robotic surgery, imaging capabilities such as PET/CT scanning and more sophisticated radiation treatment options such as CyberKnife and IMRT have contributed to this.

Finally, the introduction of many new therapeutic drugs all of which are extremely expensive has also driven up the cost of cancer care. Within the last four years, over 90% of the new drugs that received FDA approval will have a calculated cost of at least 20,000 for each drug for a 12-week cycle (**ref. #2**). There are an accumulating body of data suggesting that patients are deferring to postponing care in treatments because of the personal expenditures that these therapies entail (**ref. #1**).

As a result of this, both public and private payers are looking for ways to help control these rising expenditures. Practices are currently being caught up in this squeeze. As insurance payers attempt to decrease the cost of cancer care by decreasing reimbursements, practices are caught in the middle as indeed practice expense has risen over this period of time also. (see slide 1,2 from ET)

It is becoming more and more expensive to provide quality care in a community practice setting. The cost to deliver quality care has risen because of inflation, because of increasing regulatory burden, and because of increasing personnel necessary to deal with the paper work required by the payers. And, there will be significant costs associated with government-mandated conversion to electronic records.

The stresses and strains on practices are rapidly reaching a critical situation. Practices cannot continue to absorb falling revenues with rising costs. If this trend were to continue, this could result in dramatic change in the way that cancer care is delivered today. It is certainly conceivable that offices will close, practices would fail, and patients will be shifted back to a hospital patient setting. (This is already occurring as a result of the medicare modernization act. According to a recent survey by the ACC up to 30% of cancer care has shifted back to the hospital setting, partly due to poor reimbursement of expensive drugs and infusion codes.) This potentially could result in increased cancer cost since delivering care in a hospital-based setting is generally felt to be more expensive than that care, which is delivered in a private practice environment.

A recent action by one of the large private payers within the State of Florida has crystallized our need to take a position. This payer without any prior discussion with the oncologic community undertook a development of a program at an outside consulting agency to reduce cancer care expenditures.

The Harvest program basically involves reducing payments to physicians or drugs and services and to insert a number of pre-certification programs with the intent to decrease utilization and access to cancer care. This outside group with which the payer has contacted has no prior experience in delivery of cancer care.

The program as proposed by this payer could seriously affect the ability of all practitioners within the state of Florida to continue to provide quality care to their patients. As with this program as currently proposed, this will result in decreased utilization of services without any attempt to look at the quality of care that is being delivered. It is certainly conceivable that as care is interrupted, that the overall cost of delivering care could actually rise, as patients were shifted to alternative settings to receive their cancer care.

The Florida Society of Clinical Oncology takes strong opposition to the implementation of these types of programs, which attempt to reduce health care costs solely by restricting access and reducing payments from youth care and services.

This unilateral action prompted our professional society to begin to look at alternative methods to deliver quality care, yet continuing to help control the growing cost of cancer care. After extensive research and discussions, we feel that there are reasonable alternatives available that accomplish our objective of continuing to provide access to quality care for the citizens of Florida and to reduce the cost of cancer care to patients and payers without compromising reimbursement to private practices and allowing them to maintain their current standard of quality care to the patient community.

We feel that a program that includes utilization of clinical pathways, disease management, end of life care and steerage to preferred providers can accomplish these goals of reducing the cost of cancer care yet maintaining access quality and adequate reimbursement for the practitioners.

Currently, there is an accumulating body of evidence to suggest that these clinical pathways, which are much more specific and limited in general guidelines, can result in significant savings to the health care system. There are numerous studies in the non-oncologic literature, which showed that adherence to clinical pathways can result in significant cost savings to the health care system. A study reported in one of the journals from Europe suggested that the treatment of community-based pneumonias when based on clinical pathways could result in significant cost savings and increased efficacy and with better outcomes when most pathways were followed.

The mortality rate for patients were treated according to clinical pathways was 10% and in individuals where the patient was treated in a more generalized fashion not according to a specific pathway, the mortality rate was 13%.

Readmission rates for these patients were 2 and 6% respectively and the cost of treatments for these patients treated on pathways was 2277 Euros compared to 2567 Euros for patients who were treated in a non-pathway compliant method.

In another study looking at the control of pain, patients who were treated on clinical pathways had 25% better control of pain with fewer visits and lower cost of care. In another report looking at the use of critical pathways in brain trauma, there were input document that treatment on clinical pathways in patients with brain injury resulted in better outcomes to reduce cost.

Finally, in another report looking at the use of clinical pathways in the treatment of congestive heart failure showed that although there was increased drug usage in the patients who where treated on clinical pathways, this resulted in no increase in total cost of care and with better outcomes. The patients responded more quickly and therefore the total cost of care was not increased. (ref. #3,# 4, #5, #6, #7, #8 and #9).

Within the oncologic world, the data is less robust but there is an accumulating body of evidence to suggest that use of clinical pathways can result in significant cost savings within the cancer community.

Dr. Peter Ellis presented in managed care oncology in the 4th quarter of 2008 on work that was done at the University of Pittsburgh Medical Center with the use of clinical pathways. A program that was done in conjunction with high mark insurance, they were able to demonstrate cost savings over a period of time, individuals were complaint with pathways compared to patients treated in a non-pathway fashion. They found that they were able to control and decrease the use of avastin within this population, which results in its savings of over 1 million dollars to the health care system.

In another report from managed care oncology, a program reported by Dr. Carter and the Premiere Blue Cross Shield in Spokane, Washington, resulted in significant savings for the health care system. In this demonstration project, a practice of 22 medical oncologists were able to provide a 1 million dollar saving with the use of clinical pathways.

Currently, a pathway program has been instituted in conjunction with the Blue Cross Systems in the middle Atlantic United States with the T4 oncology group and officially there has been reporting significant cost savings.

Clinical pathways create savings by standardizing care decreasing inappropriate drug utilization. In addition, by standardization there was significant savings in nurse time allowing more nurse-patient interaction and higher quality care. There are other less well-publicized examples throughout the country where insurance companies and practices have been able to work together to utilize pathways with significant savings. There are a number of vehicles by which a pathway program can be implemented. Pathways can be developed by individual practices. In addition, there are now a number of proprietary programs available by which practices and payers make contract with established pathway program development groups.

These programs include the Innovent Program by US Oncology, the Pathway Program developed by the University of Pittsburgh Medical Center and finally the P4 Oncology Group that also works with a number of practices and physician organizations to help develop pathways for their doctors and patients. Within all of the groups, there appear to be certain characteristics that all pathways should accomplish. First and foremost, the pathways need to be developed by physicians.

Another key element to the use of pathways is that they must be evidence-based and updated on a regular schedule. There should be a mechanism for feedback from the physicians who are using the pathways as part of their clinical practice. One of the major objectives of the clinical pathway program is the standardization o treatment plans to reduce variability in administration; therefore, hopefully improving cross control and reducing the potential for medication errors.

A pathway program should include the collection of critical data points. Some of the things that should be included are cancer staging, line of therapy, tumor characteristics, performance status and the reason the treatments are altered. This may be either due to disease progression or to toxicity.

In a successful pathway program, there needs to be a minimal level of compliance to these pathways to assure success. As part of this compliance program, there needs to be feedback mechanisms that allow patients who did not fit into a pathway to receive appropriate care.

A second piece of a good coordinated cost control program includes direct patient intervention. This is often times currently done now by practices but in a very disorganized fashion. This disease management and patient intervention can be done by the practice staff, who are trained to interact directly with patients to help in education and monitoring for treatment related toxicities and side affects. A trained staff can look for treatment

toxicities and hopefully give patient interventions before the problem reached the point that require emergency room visits or hospital admissions. In addition, a trained staff can help assure that patients are compliant with taking their medications.

Compliance with oral medications is certainly growing problem with a number of oral agents rapidly increasing. There has been a study performed by the University of Michigan that shows the intervention in asthma patients helping them to monitor their compliance with drug utilization actually resulted in overall decrease in health care cost since patients who regularly took their medications had fewer emergency room and hospital visits. Although drug utilization was actually increased in this program, the cost of care was significantly reduced (**ref. #10**). Such activities undertaken by a practice need to be adequately reimbursed, any cost savings that result from this activity should be shared between the payers and the practitioners.

The third component that can result in significant cost savings in health care system is the use of a prospective end of life planning program. It is well known that patients within the Medicare system consume 30% of the total care Medicare expenditures within their last six months of life. A 25% of these are within seven days of death (**ref.#11**).

There have been a number of studies that have look through usage of hospice and chemotherapy within the final stages of patients' disease. It has been an extreme degree of variability with how these patients are treated with many patients receiving therapy that at least in some instance could have been detrimental to the patient in terms of quality of life and well being.

In one report looking at all Medicare patients who died in 2003 in Massachusetts and California, data showed that in Massachusetts 33% of patients received chemotherapy within the last six months of life with 26% receiving chemotherapy within the last six months of life in California. Within the last three months, 23% of patients in Massachusetts and 20% of patients in California received chemotherapy but within the last month of life 90% of patients in both states received chemotherapy. Certainly, much of this could have been appropriate but in many instance it probably was not (**ref. #10**).

Another report of the study done at Duke University showed that hospice use could reduce the cost of care for terminal patients. The study looked at Medicare beneficiaries, which included 1800 hospice patients and 3600 patients who were not enrolled in hospice. Hospice reduced medical expenditures within the last year of life from \$9627 to \$7318. In cancer patients, the benefit was the greatest with a \$7000 difference (**ref. #11**).

While no one is suggesting that appropriate care be denied to cancer patients, it is clearly evident that some patients are receiving treatments with little benefit. There is little data supporting the use of chemotherapeutic agents past a third line therapy in lung cancer if surgery shows that this happens not infrequently. In addition, patients with extremely poor performance status at level 3 are sometimes treated with systemic chemotherapy with again chances for significant response being very minimal.

Certainly, these patients may be more appropriately managed with palliative care and symptom control resulting in better quality of life in the terminal stages of disease with significant cost savings. Practices are actively involved in advanced planning should be recognized for this and savings that are obtained for the appropriate use of palliative care should be shared between patients and providers.

A final way in which significant status can be brought to the health care system includes the use of steerage. Within all programs, there are high quality providers who provide good services if you offer significant differences in their reimbursement rates. By directing patients to providers who offer the most competitive rates, significant savings can be obtained. In addition, the use of tiered co-pays and deductibles, patients can be directed to practices who follow pathways for higher quality care and in a most cost efficient manner. Again savings obtained by this system should be shared between providers and payers. The Florida Society of Clinical

Oncology remains committed to the delivery of high quality cost affective medical care to the cancer patients of Florida. Our hope is that cancer care provider community can work together with the payers and employers and patients of the state to assure that patients are not denied care that is of the highest quality. We firmly believe that embarking upon a program that includes some of the principles discussed above that the highest quality of care could be delivered in a very cost effective manner that significant savings of the health care system.

Reference #1: Marpel: The cost of cancer care in the American Society of Clinical Oncology Guidance Statement Journal of Clinical Oncology volume 27, #23 August 10, 2009.

Reference #2: Medscape Medical Moves July 14, 2009.

Reference #3 Menendez Economic Evaluation of Guidelines of Pneumonia, European Respiratory Journal, volume 29.

Reference #4: Fritz Guideline Adherence and Outcomes, medical care volume 45, #10 October 2007.

Reference #5: Cost benefit of BTF guidelines, journal of trauma volume 63, #6 December 2007 DiDomeniec outcomes associated with acute congestive heart failure guidelines, the annuals of pharmacology volume 42, March 2008.

Reference #7: LS discussion on guidelines Managed Care Oncology, Fourth Quarter 2008.

Reference #8: Cutter: Can an insurance company and oncology practice work together managed care oncology 2009 in print.

Reference #9: Schaffer implementation of clinical guidelines in a practice perspective, the oncologic volume 8, #2 December of 2009.

Reference #10: Emaneul chemotherapy use amongst Medicare beneficiaries at the end of life and open internal medicine volume 35, 2003.

Reference #11: Taylor what length of hospice use maximizes reduction in medical expenditures near death in US Medicare population, Social Science and Medicine volume 65 June 2007.

TABLE I

Components of Effective Value Program

1. Standardization of treatment
2. Disease Management
3. End of Life Care
4. Steerage to Cost effective Providers

TABLE II

Key Principles of an effective Pathway Program

1. Physician developed
2. Evidence based
3. Regularly reviewed
4. Mechanism for feedback by those using the pathways
5. Ability to collect key data end point
6. Monitoring compliance and feedback with practitioner